No. _____

IN THE

Supreme Court Of The United States

FLEUR T. TEHRANI,
Petitioner,

v.

POLAR ELECTRO AND POLAR ELECTRO OY
AND
PHYSI-CAL ENTERPRISES,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether the Court of Appeals for the Federal Circuit erred by affirming the district court's ruling, holding that the petitioner dedicated numerous embodiments of U.S. Patent No. 4,909,259 to the public because the word "patient" used in the claims cannot encompass healthy individuals.

Whether the Court of Appeals for the Federal Circuit erred by affirming the district court's ruling that excluded numerous embodiments, including the simplified preferred embodiment of U.S. Patent No. 4,909,259 and concluding that the claimed invention was limited to its most detailed embodiment.

Whether the Court of Appeals for the Federal Circuit erred by affirming the district court's ruling, holding that numerous embodiments of U.S. Patent No. 4,909,259 were dedicated to the public without providing any opinion or justification.

PARTIES TO THE PROCEEDING

One of the defendants-appellees in the proceeding in the Court of Appeals for the Federal Circuit, Cat Eye Co. LTD, has settled with the appellant and is not a party here. Pursuant to Rule 14.1(b), the remaining parties in the U.S. Court of Appeals for the Federal Circuit which are parties here are listed below:

Petitioner is Fleur T. Tehrani, PhD, an individual.

Respondents are Polar Electro Inc., and Polar Electro Oy (collectively "Polar"), and Physi-Cal Enterprises, Inc., ("Physi-Cal").

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The petitioner is an individual. No interest of the petitioner in this case is assigned to any corporation or any publicly held company.

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PETITION FOR A WRIT OF CERTIORARI

Fleur T. Tehrani, PhD, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The decision of the court of appeals (App. I-1-App. I-2) was entered on December 5, 2008 and is not reported. The final judgment of the district court (App. I-3-App. I-31) was entered on October 4, 2007 and is not reported.

JURISDICTION

The decision of the Court of Appeals for the Federal Circuit issued on December 5, 2008. The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 271 of the Patent Act, 35 U.S.C. § 271, provides in relevant part:

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.

STATEMENT OF THE CASE

A. Introduction

This case involves a district court's interpretation of the claims of Petitioner's patent and its resulting summary judgment of non-infringement based on that interpretation. The district court in this case excluded and dedicated to the public several embodiments of the petitioner's patent based on the term "patient." The district court held that "patient" could not encompass "healthy individuals," contrary to the patent claims, written specification, and the ordinary meaning of the term. Contrary to its own precedent, the Court of Appeals for the Federal Circuit affirmed this ruling, without providing any opinion or other explanation. While this Court has held that claim construction is a question of law for the Court, see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996), this Court has not since substantively commented on the process by which courts should interpret patent claim terms. This case presents an opportunity to do so.

B. The Patented Invention

Metabolic rate is the rate at which a person expends energy and the metabolic rate ratio is the ratio of this energy expenditure rate to basal rate of metabolism (basal rate of metabolism is metabolic rate at complete rest). The petitioner, Fleur T. Tehrani, has been a professor of electrical engineering at California State University for more

than twenty three years. During her course of research, she discovered that a person's metabolic rate ratio could be conveniently determined by using data indicative of a cardiac function. In 1987, the existing monitors were either too cumbersome to use or highly inaccurate. Ms. Tehrani developed a system using her derived mathematical equations and procedures to overcome the existing problems at that time and built a prototype of her invention in the fall of 1987. She filed a patent application on her invention in April 1989, and the United States Patent and Trademark Office awarded her U.S. Patent No. 4,909,259 (the '259 Patent) on March 20, 1990. (App. II-1-App. II-20)

The patented technology was useful both for persons undergoing medical treatment for various illnesses and for healthy persons using exercise equipment who wished to determine how much energy they were expending while exercising. The most detailed embodiment of this invention, which was suited for non-healthy persons, used either a cardiac output monitor or a heart rate sensor accompanied by a stroke volume monitor which is a hospital measuring equipment, as well as carbon dioxide and oxygen gas analyzers to analyze respiratory gases. This detailed embodiment utilized a series of equations 1-9 of the patent (App. II-15, at 7:60-67; 8:1-51) to determine the metabolic rate ratio (MRR). However, MRR could be more simply determined for healthy individuals. The most simplified embodiment of the patent for healthy persons used only a heart rate monitor to determine MRR. In this embodiment, no gas analyzers were

needed and the system algorithm utilized the person's heart rate data along with a constant representative value of stroke volume stored in software to determine MRR using equations 8 and 9 of the patent only (App. II-15, at 8:46-51).

C. The Claims at Issue and the Simple Exercise Monitoring Embodiment of the Patent

Claim 1, the only independent claim at issue recites:

1) Apparatus comprising:
(a) first means for providing data indicative of a cardiac function of a patient; and,
(b) second means for determining the patient's metabolic rate ratio based upon the data provided by the first means.

Dependent Claims 6 and 8 at issue recite:
6) Apparatus according to claim 1 wherein the first means comprises a heart rate monitor.

8) Apparatus according to claim 6 wherein the heart rate monitor comprises means for processing an ECG signal.

(App. II-17, Claims 1, 6, and 8).

As seen, in Claim 1, the "first means" provides data indicative of "a cardiac function," and the "second means" determines the patient's metabolic rate ratio based on that data. The term "cardiac function," does not have any single specific meaning

in the scientific literature and a number of terms are used in reference to this terminology. For example, the textbook *Mechanical Ventilation: Physiological and Clinical Applications* contains a section titled "Terms Specific to Cardiac Function," which explains that the following terms are frequently used in reference to cardiac function: "heart rate, pulse pressure, stroke volume, cardiac output, cardiac index, preload, contractility, afterload, and vascular resistance." *Susan P. Pilbeam, M.S., R.R.T., Mechanical Ventilation: Physiological and Clinical Applications* 433 (2d ed. 1992), App. I-34.

The '259 Patent discloses multiple means for providing data indicative of a cardiac function, including methods and structures for monitoring heart rate, cardiac output, and stroke volume. The various structures and methods are disclosed throughout the specification (App. II 13, at 4:28-32; 39-45, App. II-14, at 5:30-35; 43-48; 51-56). When properly construed, the first means of claim 1 requires a heart rate monitor, a cardiac output monitor, or a heart rate monitor accompanied by a stroke volume monitor.

As to heart rate data, the Patent explains:

"Various techniques have been described in the prior art for measuring heart rate. U.S. Pat. Nos. 4,034,745, 4,181,134, and 4,239,048 are representative." (App. II-12, at 1:60-63).

The '259 Patent, however, is not limited to this disclosure and lists additional structures and methods for measuring heart rate as:

A pulse detector 26 may provide a systolic pulse signal 28 to counter circuit 30. A pulse detector with a photoelectric cell transducer may be used to detect systolic pulses of the subject, for example, at the finger. Alternatively, the patient's ECG signal can be provided as the input to counter 30.

App. II-14, at 5:51-56.

As to stroke volume, the patent reads:

The patient's stroke volume *may* comprise another input to processor 32. *If provided,* the stroke volume can either be continuously monitored using an appropriate noninvasive measuring technique or measured prior to operation of the system at any desired posture and applied as a constant input to the system. The latter is possible since stroke volume is affected mainly by the subject's posture and, after a slight increase during the transition from rest to exercise, remains fairly constant at different levels of activity. Stroke volume may be measured by a monitor 56 of a type described above and an analog output 54 therefrom, representing the patient's stroke volume, may be applied to the input of an A/D converter 50. App. II-14, at 5:30-43 (emphasis added).

Therefore, the above passage shows that stroke volume may or may not be input to the processor, and when used as input, it can be regarded as a constant. Its value can be measured by a noninvasive

monitor such as the ones described in the patent and provided to the system.

However, a stroke volume monitor is a hospital device and it is impractical to use such a device in a simple exercise monitoring system for running, jogging, etc., for healthy people in exercise. Therefore, the patent further states:

> *Alternatively,* if it is not desired to monitor stroke volume continuously, a representative value (e.g., obtained from the patient prior to operation of the system) may be stored in software of the processor 32 or supplied to the input of A/D converter 50 from a fixed adjustable voltage source 58.

App. II-14, at 5:43-48 (emphasis added).

Therefore, in an *alternative* technique when stroke volume is not measured, a constant value can be stored in the system software to represent stroke volume. In this case, the first means of Claim 1 is a heart rate monitor providing heart rate data and stroke volume is not input to the processor but is represented by a constant in software. This is the configuration of the simple exercise monitoring embodiment of the '259 patent with regard to providing data indicative of "a cardiac function" of a patient.

The above construction is also in conformance with the ordinary definitions of the terms "cardiac" and "function." Cardiac is defined as "pertaining to the

heart." *Webster's New Twentieth Century Dictionary* 273 (2d ed. 1983). App. I-41. A standard dictionary like *Webster's*, however, lists multiple definitions for the common term "function." The words of the claim term itself, "*cardiac* function" and the '259 patent's specification provide ample guidance of which definition is proper. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1319-24 (Fed. Cir. 2005) (*en banc*) (explaining that because general use dictionaries provide multiple definitions for words as used in multiple fields, the specification and claims must always be consulted to ensure that a definition is not being arbitrarily chosen). Here, the term "cardiac" clearly modifies "function," suggesting that the most appropriate definition would relate to physiology or biology. The nature of the invention, *i.e.* metabolic rate monitoring, likewise supports this position. In light of the surrounding claim terms and the invention as a whole, the most appropriate definition for function is "the normal or characteristic action of anything; especially, any of the natural, specialized actions of an organ or part of an animal or plant." *Webster's New Twentieth Century Dictionary* 741 (2d ed. 1983) App. I-41. Therefore, the ordinary meaning of "a cardiac function" is "any of the natural, specialized actions of the heart." Accordingly, the extrinsic evidence further supports construing "a cardiac function" to simply mean heart rate since heart rate is a natural, specialized action of the heart.

The structure of the second means of Claim 1 is a digital processor, such as a microprocessor, programmed to carry out the algorithm disclosed in

the flow chart of Figures 3A-3D of the patent (App. II-4-App. II-7). *See WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999). The '259 patent discloses multiple algorithms, each of which is a distinct and alternative structure for determining MRR. As a result, the structure corresponding to the second means element is a digital processor programmed to carry out any one or more of the algorithms for determining metabolic rate ratio described in the '259 patent. *Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1345 (Fed. Cir. 2002) (holding that even though the specification disclosed four separate algorithms for correcting different types of errors, the corresponding structure to the "means for offsetting" is not limited to a single computer programmed to correct all four types of errors).

The steps in the algorithm in figures 3A-3D of the patent and the mathematical equations needed to perform the claimed function – determining the patient's metabolic rate ratio based upon the data provided by the first means – necessarily depends on the data provided by this first means.

The '259 patent provides a number of equations that can be used in the determination of metabolic rate ratio. Some of those equations relate to the effect of arterial CO_2 and O_2 gas pressures (*see* Equations 2-7 (App. II-15, at 8:1-40), while other equations relate to cardiac output, including heart rate and stroke volume data. *See* App. II-15, at 8:46-52. As the '259 patent describes, however, not all those equations are necessary in the determination

of MRR in every embodiment of the invention. As the patent explains:

> The apparatus and method disclosed herein may be simplified if used for normal, healthy individuals. For a healthy subject, the arterial pressures of CO_2 and O_2 in light-to-moderate exercise remain within a normal range at rest. Under these conditions, $Q'(CO_2)$ and $Q'(O_2)$ from equations 3 and 5 will be zero, and there is no need to use CO_2 and O_2 sensors in the system.

App. II-16, at 9:7-13. Accordingly, provision of data from CO_2 and O_2 sensors which is a requirement of unasserted dependent Claims 2 and 3, is not a requirement of Claim 1 (App. II-17, Claims 1, 2, & 3).

Therefore, when the first means in Claims 1 and 6 (*Id.*) is properly construed, the CO_2 and O_2 data are not needed for the simple embodiment and heart rate is the only cardiac function data provided by the 1st means. The outputs of equations 3-5 will be zero (*see* App. II-16, at 9:11-13), the equations relating to arterial gas pressures need not be used in the determination of MRR, and consequently, only equations 8 and 9, from Column 8 of the patent, are used to determine MRR (App. II-15, at 8:45-52). Equations 8 and 9 of the '259 patent constitute a system of two algebraic equations that can be solved to find MRR as a function of heart rate. To solve this system of equations, heart rate at rest which is entered in the system can be used to find stroke

volume from equations 8 and 9 since MRR =1 at rest. Then the representative constant value for stroke volume is used at other heart rates to determine MRR.

Therefore, when properly construed, first means of Claim 1 can be a heart rate monitor only providing "a cardiac function" data that is heart rate to the second means. The second means which is a digital processor uses the heart rate data and performs the necessary steps of the flow chart using only equations 8 and 9 of the patent in the simple embodiment, to determine MRR, by using a constant representative value for stroke volume that can be in terms of heart rate at rest.

Claim 6 of the '259 patent that depends from Claim 1 requires the first means to comprise a heart rate monitor, and Claim 8 that depends from Claim 6 requires the heart rate monitor to comprise means for processing the patient's ECG signal.

D. The Defendants' Infringement

Petitioner filed suit for patent infringement against Polar, Phsi-Cal, and another defendant on November 14, 2005, alleging that various exercise monitoring devices sold by the defendants infringed Claims 1, 6, and 8 of the '259 patent. The alleged infringing devices all included heart rate monitors providing "data indicative of a cardiac function," and they all determined MRR based on that data, in a manner literally infringing the '259 patent according

to the disclosed simplified exercise monitoring embodiment of the invention.

E. The District Court Proceedings and Rulings

In the course of the litigation, the district court instructed the parties to file claim construction briefs in conjunction with summary judgment motions. The court held a hearing on the summary judgment and claim construction motions on July 24, 2007.

On October 3, 2007, the district court issued a minute order vacating the pretrial and trial dates, indicating that the court was granting summary judgment of noninfringement. The court denied the plaintiff's motion for summary judgment of infringement, granted summary judgment of noninfringement in favor of the defendants, and stayed the defendants' invalidity and unenforceability counterclaims. The court directed entry of final judgment pursuant to Fed. R. Civ. P. 54(b) on October 4, 2007. (App. I-3-App. I-31).

The court's ruling on noninfringement was based on claim construction. In its ruling, the district court focused on the term "patient" in Claim 1. The court refused to definitively construe this term, but held that, at a minimum, it could not encompass healthy individuals. Based on that holding, the court "dedicated" the simple embodiment of the '259 patent relating to healthy individuals to the public. The court also adopted an overly narrow definition for claim term "a cardiac function," to mean "cardiac output," based on its dedication holding. On the basis

of this construction of Claim 1, the court then adopted the most detailed structure of the second means of the claim, requiring it to comprise the most detailed software and equations 1-9 of the '259 patent, without further elaboration. By this ruling, the district court held that the simple embodiment as well as other embodiments disclosed in the patent that use only heart rate as "a cardiac function" or do not require inputs from gas sensors to determine MRR were not covered by any of the patent claims. Only the most detailed embodiment of the patent remained undedicated.

F. The Flaws of the District Court Ruling

1. The District Court Erred by Dedicating the Simplified Embodiment of the '259 Patent to the Public Based on the Term "Patient."

a. The term "patient" is not used to distinguish between the embodiments of the '259 patent.

Federal Circuit has repeatedly held that a construction that excludes a preferred embodiment is rarely, if ever, correct. *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003); *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Such a construction "would require highly persuasive evidentiary support." *Id.*

The basis for the district court's claim construction leading to dedication of several embodiments of the

'259 patent including its simplified exercise monitoring system is the term "patient." Yet, rather than citing any highly persuasive evidence, the district court declined to construe this disputed term. Instead it stated:

> As to the term "patient," the Court agrees with . . . [defendants] that it need not be explicitly defined, except to note that because of the term's juxtaposition with the contrasting "normal, healthy individual," regardless of its exact definition, the term "patient" in the '259 patent indicates something other than a "normal, healthy individual."

App. I-10-App. I-11.

The district court provided no analysis or explanation as to how the '259 patent "juxtaposes" or "contrasts" the terms "patient" and "normal, healthy individual." Based on its conclusion, the court stated:

> Despite the disclosure of different apparatuses for different classes of individuals, the claims at issue are specific to the "patient" apparatus. None of the claims are directed to the embodiment for "normal, healthy individuals," "normal healthy subjects" or any other generic term that could encompass both patients and normal, healthy individuals, such as "individual," "subject," or "person."

App. I-7.

The court further concluded:

> The problem is that Dr. Tehrani did not employ such generic terms, instead she chose to limit each of the claims at issue to the cardiac function of a "patient." Therefore, because Dr. Tehrani did not claim the disclosed simplified "normal, healthy individual" embodiment, it is dedicated to the public.

App. I-14.

However, as explained below, the written description of the '259 patent as well as the ordinary meaning of the terms "patient" and "subject" contradict, rather than support the district court's conclusion.

The '259 patent specification uses the terms "subject," as well as "individual," when discussing the simplified embodiment:

> Referring now to the drawings . . . there is illustrated in FIG. 1 . . . a preferred embodiment of a measuring/monitoring system provided in accordance with this invention . . . . As shown, exhaled gas from a *patient* is passed through an expiration line 60. Expiration line 60 is coupled at one end to CO_2 and O_2 sensors 46, 48 via inlets 62, 64. . . . The exhaled gases from the *patient* are analyzed by the CO_2 and O_2 sensors

> 46, 48 to provide data indicative of the *patient's* concentrations of CO_2 and O_2, respectively. (If system 10 is employed as an exercise monitoring system for a *normal healthy subject*, analysis of the exhaled gases will not be necessary since the arterial pressures of O_2 and CO_2 for the *subject* in light to moderate exercise do not differ significantly from their normal values at rest.)

App. II-13-App. II-14, at 4:58-5:8 (emphasis added).

The term "healthy individuals" is used only once in the entire specification and, as shown below, it is used interchangeably with the term "healthy subject."

> The apparatus and method disclosed herein may be simplified if used for normal, *healthy individuals*. For a *healthy subject*, the arterial pressures of CO_2 and O_2 in light-to-moderate exercise remain within a normal range at rest. Under these conditions . . . there is no need to use CO_2 and O_2 sensors in the system.

App. II-16, at 9:7-13 (emphasis added).

Therefore, the '259 patent uses the terms "individual" and "subject" interchangeably. The patent also repeatedly uses the terms "patient" and "subject" interchangeably. For example, the specification provides the following:

> The *patient's* stroke volume may comprise another input to processor 32. If provided, the stroke volume can either be continuously monitored . . . [or] applied as a constant input to the system. The latter is possible since stroke volume is affected mainly by the *subject's* posture. . . . Stroke volume may be measured . . . and an analog output 54 therefrom, representing the *patient's* stroke volume, may be applied to the input of an A/D converter 50.
>
> A pulse detector 26 may provide a systolic pulse signal 28 to counter circuit 30. A pulse detector with a photoelectric cell transducer may be used to detect systolic pulses of the *subject*, for example, at the finger. Alternatively, the *patient's* ECG signal can be provided as the input to counter 30.

App. II-14, at 5:30-43; 51-56.

This repeated interchangeable use demonstrates the breadth of these terms, not that they are exclusive of one another or used to distinguish between disclosed embodiments. In other words, the patentee intended them to have the same meaning. *See Bicon, Inc. v. The Straumann Co.*, 441 F.3d 945, 953 (Fed. Cir. 2006); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1375 (Fed. Cir. 2005). Accordingly, the district court erred when it excluded a preferred embodiment from the Claims based on a perceived "juxtaposition" or "contrast" between embodiments based on these terms.

b. When given their ordinary meanings, "patient" and "subject" are not mutually exclusive terms.

As explained above, the district court did not construe the term "patient." Had the court done so, it would have been evident that the patent does not use the terms "patient" and "subject" as mutually exclusive terms and that those terms cannot serve to distinguish between embodiments in the '259 patent.

In *Agfa Corp.* v. *Creo Prods., Inc.*, 451 F.3d 1366, 1376 (Fed. Cir. 2006), the Federal Circuit explained that "the ordinary meaning of some claim terms 'may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words.'" The ordinary dictionary definitions of "patient" and "subject" are provided below.

Patient: 1. a person who is under medical care or treatment. 2. a person or thing that undergoes some action. *The Random House Dictionary of the English Language*, 1421 (2d ed. unabr. 1987). (App. I-35.)

Subject: a person or thing that undergoes or may undergo some action. *Id.* at 1893. (App. I-36).

These definitions show that "patient" and "subject" are not antonyms; nor are they mutually exclusive.

Indeed, the second definition of "patient" is nearly identical to the definition of "subject." In this case, as detailed above, the '259 patent uses the terms "patient" and "subject" interchangeably. Thus, consistent with the common definitions of "patient" and "subject," the '259 patent uses the terms "patient" and "subject" interchangeably to mean simply a person that undergoes some action – namely, in the context of the patent, a person that undergoes some testing with the disclosed invention to determine his or her metabolic rate ratio.

Moreover, the mere addition of the adjective "healthy" to "subject" does not render it incompatible with the term "patient." Neither the ordinary meaning of "patient" nor the '259 patent requires a patient to be "sick" or "unhealthy." Nor does seeking medical care render a person unhealthy. Healthy people routinely seek medical care for preventative purposes. Expecting mothers seek medical care throughout their pregnancies. They are "patients" within the normal meaning of that term, even if they are not unhealthy or sick. Indeed, millions of Americans carrying health insurance under HMOs are "patients" of, and under the medical care of, their insurer's primary care physicians, regardless of whether they are "sick" or "healthy." They are "patients," even though they are not unhealthy or sick. Thus, "patients" can be divided into both "healthy" and "unhealthy" groups, and a person classified as "normal" and "healthy" does not thereby lose his status as a "patient." Properly construed, any "patient" can be in either the "healthy" group or the "unhealthy" group.

c. When properly construed, the asserted claims cover the preferred simplified exercise embodiment.

As shown above, the written description, the ordinary meaning of the claim language, and the other claims all evidence that the preferred simplified exercise embodiment is within the scope of the asserted claims. The term "patient" is broad enough to encompass all persons undergoing testing while exercising to determine their metabolic rate ratios regardless of their health, as described in the patent specification. There is no "highly persuasive evidentiary support" for the district court's contrary conclusion excluding the simplified preferred embodiment from the scope of the claim. Accordingly, the district court's holding is erroneous as a matter of law.

2. The District Court Erred in Construing the Term "A Cardiac Function"

a. The district court limited the term "a cardiac function" based on its erroneous dedication of the simple embodiment.

As was described in section C above, "a cardiac function" data provided by the first means in Claim 1 can be heart rate alone, heart rate accompanied by stroke volume data, or cardiac output. In its ruling the district court stated:

> The normal healthy individual embodiment is discussed only twice in the specification, both times as a potential simplified version of the patient embodiment. See Pl.'s Ex. A, Patent Col. 5, lns. 3-8, Col. 9, lns. 7-13. Given this disclosure, if Claim 1 claimed an apparatus comprising first means for providing data indicative of the cardiac function of a subject, an individual, a person, or some other generic term, Claim 1 would cover both embodiments disclosed in the specification. The problem is that Dr. Tehrani did not employ such generic terms, instead she chose to limit each of the claims at issue to the cardiac function of a "patient." Therefore, because Dr. Tehrani did not claim the disclosed simplified "normal, healthy individual" embodiment, it is dedicated to the public.

App. I-14.

Therefore, the district court dedicated the simplified embodiment of the patent that required the first means of Claim 1 to provide only heart rate data to the second means, and determined that due to the use of the word "patient" in Claim 1, "a cardiac function" data provided by the first means had to include stroke volume data as well as CO_2 and O_2 gas concentration data along with heart rate. As was discussed above, the word "patient" in the '259 patent is *not* used to distinguish between the embodiments and the logic adopted by the district court is flawed.

b. The district court erred by limiting "a cardiac function" to mean "cardiac output."

The district court at the urging of the defendants and in order to strengthen its "dedication" holding, construed the term "a cardiac function" to mean "cardiac output." As shown below, the intrinsic and extrinsic evidence supports a broader interpretation.

The Federal Circuit has frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips*, 415 F.3d at 1312. This "ordinary and customary meaning . . . is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. . . ." *Id.* at 1313. Nonetheless, the Federal Circuit has also recognized that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316. As explained below, however, the Federal Circuit requires that, where the patentee is providing a special definition, that definition must be unambiguous.

"When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description. *See, e.g., Bell Atl. Network Servs. v. Covad Comm. Gp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001); *see also Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214

F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning."); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998) ("The patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim."); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1177-78 (Fed. Cir. 2002) (stating that the "presumption in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence").

Despite this well settled precedent, the district court reached its decision that the '259 patent "expressly" defines the term "a cardiac function" by relying almost entirely on a single ambiguous reference from the '259 patent's Abstract, which provides that "[t]he cardiac function data *may be* either heart rate and stroke volume of the patient, or cardiac output data . . . ." (emphasis added). This recitation of two acceptable types of "cardiac function data" does not clearly and deliberately limit "data indicative of a cardiac function" to those two forms of data. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 912-13 (Fed. Cir. 2004) ("it is improper to read limitations from a preferred embodiment disclosed in the specification—even if it is the only embodiment—into the claim absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited."). Contrary to the district court's conclusion, this brief reference in

the Abstract does not clearly and deliberately define "a cardiac function."

The '259 patent employs different language when it intends to supply a definition of a term, as opposed to when it intends merely to provide examples of things coming within the scope of a term. The '259 patent unambiguously defines another term, "metabolic rate ratio," explaining that "MRR *is* the ratio of the metabolic rate to basal rate of metabolism." App. II-12, at 1:57-58 (emphasis added). In contrast, in referring to "cardiac function" the '259 patent Abstract provides "[t]he cardiac function data *may* be either heart rate and stroke volume of the patient, or cardiac output data . . . ." App. II-1 (emphasis added). In other words, '259 patent unambiguously defines metabolic rate ratio by affirmatively stating "MRR is. . ." something, whereas it injects qualifying language when it explains what "cardiac function data *may*. . ." be. Accordingly, MRR is clearly and deliberately defined, whereas "cardiac function" is not.

Similar attempts by district courts to narrowly construe ambiguous disclosures as "express" definitions repeatedly have been rejected by the circuit court. *See Abbott Labs. v. Andrx Pharma., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007), and *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1121 (Fed. Cir. 2004).

Therefore, the statement relied upon by the district court in the '259 patent Abstract is not an

express definition of "a cardiac function," and cannot be used to limit the term to "cardiac output."

c. The district court's construction is contrary to the teachings of the '259 patent.

By limiting "a cardiac function" to "cardiac output," the district court unduly required that when heart rate data was provided by the first means of Claim 1, it had to be accompanied by provision of stroke volume data from a stroke volume monitor by the first means. This requirement is against the teachings of the patent. The following passage of the '259 patent talks in detail about provision of stroke volume data:

> The patient's stroke volume *may* comprise another input to processor 32. *If provided,* the stroke volume can either be continuously monitored using an appropriate noninvasive measuring technique or measured prior to operation of the system at any desired posture and applied as a constant input to the system. The latter is possible since stroke volume is affected mainly by the subject's posture and, after a slight increase during the transition from rest to exercise, remains fairly constant at different levels of activity. Stroke volume may be measured by a monitor 56 of a type described above and an analog output 54 therefrom, representing the patient's stroke volume, may be applied to the input of an A/D converter 50.

App. II-14, at 5:30-43 (emphasis added).

Therefore, according to the patent, stroke volume *may* or *may not* be provided as input, and *if provided,* it can either be continuously monitored by using monitors such as the ones described in the patent, or it can be measured at any desired posture and applied as a constant to the system. The patent further states:

> *Alternatively,* if it is not desired to monitor stroke volume continuously, a representative value (e.g., obtained from the patient prior to operation of the system) may be stored in software of the processor 32 or supplied to the input of A/D converter 50 from a fixed adjustable voltage source 58.

App. II-14, at 5:43-48 (emphasis added).

Hence, in an *alternative* arrangement to the ones previously mentioned, in which stroke volume was measured using a monitor, *a representative value* may be stored in the software of the processor or applied to the system from a fixed adjustable voltage source. Therefore, it is clear that, contrary to the district court's ruling, there is no mandate in the patent that when stroke volume data is stored in software, it still has to be measured by a monitor and provided to the processor by the first means. All that is required is a "representative value" of stroke volume saved in the software. That representative value can be obtained as a generic value, or it can be obtained by using heart rate at any point where

MRR is known (such as rest) from equations 8 and 9 of the patent that are the only equations needed in the simplified embodiment of the patent as shown in section C above. Stroke volume can be represented in terms of heart rate at rest that is entered in the system as shown above and used to determine MRR at different levels of activity using heart rate data alone.

Indeed, when stroke volume is a constant in the system software, the heart rate data which is "a cardiac function data," will serve to indicate cardiac output of the user since the product of heart rate and a constant number for stroke volume is cardiac output. Accordingly, the proper construction of "a cardiac function" in Claims 1 and 6 includes heart rate alone.

d. The language of the asserted and unasserted claims also demonstrate that the district court's construction was erroneous.

Asserted Claim 6 provides:

6) Apparatus according to claim 1 wherein the first means comprises a heart rate monitor.

Unasserted Claim 9, which depends from Claim 6 provides:

9) Apparatus according to Claim 6 further comprising a stroke volume monitor

App. II-17, Claims 6 and 9.

The only meaningful difference between claim 6 and its dependent claim 9 is the addition of the limitation "a stroke volume monitor." The district court reasoned that since the patent claims use the word "comprises," and the term "a cardiac function" means "either heart rate and stroke volume or cardiac output" based on the term "patient" and the Abstract, Claim 9 merely dictates the type of structure that is needed to provide that data. App. I-20, App. I-21. Thus, the district court stated that "Claim 1 permits either type of monitor (cardiac output or stroke volume *plus* heart rate)." App. I-20 (emphasis added). In so reasoning, the district court ignored the terms of claim 6, which explicitly recites a heart rate monitor *without* specifying the stroke volume monitor (added in dependent claim 9). By construing "a cardiac function" to *always* require a stroke volume monitor if heart rate is monitored, the district court's claim construction impermissibly renders Claim 9 superfluous. *Liebel-Flarsheim*, 358 F.3d at 910.

Moreover, the language of several other unasserted claims demonstrates that the district court's construction is without merit. Claims 14, 15 and 16, which depend from Claim 11, further demonstrate that the '259 patent does not require stroke volume data in addition to heart rate data to determine MRR. Claim 11 is an independent claim requiring only heart rate as cardiac function data. App. II-17, Claim 11. Claim 14 further limits Claim 11, requiring a fourth means for providing data

indicative of stroke volume. App. II-17, Claim 14. Thus, interpreting the means for determining MRR in Claim 11 to include means for providing data indicative of stroke volume would impermissibly render Claim 14 superfluous. *Id.*

Likewise, Claims 15 and 16 further restrict Claim 14 to either providing data indicative of stroke volume by continuously monitoring it or supplying a constant value. App. II-17, Claims 15 and 16. Thus, it would be incorrect to interpret Claim 11 as already containing these limitations because it would render Claims 15 and 16 superfluous. *Id.*

e. The extrinsic evidence likewise contradicts the district court's construction.

The extrinsic evidence made of record at the district court further supports the construction of "a cardiac function" set forth above. Multiple textbook definitions of "cardiac function" that include "heart rate" alone, and definitions of the terms "cardiac" and "function" by standard dictionaries provide that the ordinary definition of "a cardiac function" is "any of the natural, specialized actions of the heart," as was shown in section C above. Accordingly, the extrinsic evidence further supports construing "a cardiac function" to not require "stroke volume" as a component. Simply put, heart rate data is "data indicative of a cardiac function."

f. The district court improperly imposed structural limitations that are not required to perform the recited functions.

When construing means-plus-function claims, the district court erred in dedicating and excluding several embodiments of the '259 patent including the simplified exercise embodiment based on a narrow interpretation of the term "patient" and construing the term "a cardiac function," to always mean "cardiac output." Due to those errors, the district court incorporated structural limitations into Claim 1 that are unnecessary to perform the recited functions. Specifically, the district court construed the first means as requiring (1) sensors to measure arterial CO_2 and O_2 gas pressures, (2) structure to provide heart rate as well as stroke volume data or a cardiac output monitor, and (3) structure "to provide the data used by equations 1-9 of the '259 Patent." App. I-24.

Limiting claim 1 to those particular structures contradicts the disclosure of the '259 patent specification. In sum, the first means of Claim 1 is a heart rate monitor alone when a constant representative value for stroke volume is stored in software. No structure is needed in the first means to provide stroke volume data to the processor when a representative constant for such data is stored in software. Indeed, since a stroke volume monitor is a hospital-based measuring device, if the simple exercise monitoring embodiment required the

inclusion of such a monitor, which it does not, it would have been completely impractical to use for healthy people in exercise. No gas analyzers are required to be included in the first means of Claim 1 and the structure of the second means performs the simplified algorithm using equations 8 and 9 of the patent to determine MRR as shown above.

G. The Federal Circuit Proceedings

The Petitioner timely appealed to the Court of Appeals for the Federal Circuit on November 5, 2007. Oral argument was held on August 8, 2008. Four months after the oral argument, the Federal Circuit affirmed the district court's judgment without opinion under Federal Circuit Rule 36. No further explanation or analysis was provided. (App. I-1-App. I-2).

H. The Federal Circuit Decision Is In Error And Needs To Be Reversed.

As explained above, the district court improperly dedicated several embodiments of the '259 patent to the public based on its interpretation of the word "patient" to refer to only sick persons.

During the hearing before the circuit court judges, Judge Rader repeatedly questioned the defendants on the term "patient." He stated:

> I don't see anywhere here that the patent has defined patient to exclude a normal person. In fact, I think it is exactly the other way around.

> It has included within its claimed invention an embodiment that covers normal healthy people. So obviously, a patient is a normal healthy person too.

Audio recording of the hearing posted at: http://oralarguments.cafc.uscourts.gov/searchscript.asp

Since the incorrect interpretation of the term "patient" is the primary basis for the district court's ruling, that ruling should have been reversed by the Federal Circuit. Instead, the Federal Circuit merely affirmed without any explanation whatsoever.

I. The Reasons That This Petition Should Be Granted

1. This petition should be granted to prevent the dedication of patentees' rights to the public without any justification.

As this Court has held, the patent system is authorized by the United States Constitution and plays an important role in encouraging innovation. *Markman*, 517 U.S. at 373; *Diamond v. Chakrabarty*, 447 U.S. 303, 307, 100 S. Ct. 2204, 2206-07, 65 L. Ed. 2d 144 (1980). A recent study showed that eight of top ten most innovative countries in the world were among the top ten in strength of patent protection. *Edwin Lai, Intellectual Property Protection in a Globalizing Era: Insights from the Federal Reserve Bank of Dallas,* ECONOMIC LETTER, Vol. 3, No. 3,

at 5 (Mar. 2008). This study concluded that inadequate patent protection "greatly discouraged" innovation. *Id.* at 4.

The United States has been at the forefront of innovation and achieved its technological advances due to numerous valuable inventions. In fact, the importance of patents in promoting innovation was realized by the Founding Fathers of this country. The Patent Act "embodie[s] Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'" *Chakrabarty,* 447 U.S. at 308-09 (quoting 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871)).

Accordingly, patent rights must be upheld and respected by the courts of law. In this case, the district court dedicated several embodiments of the patent to the public based on its incorrect interpretation of the term "patient." The district court held, and the Federal Circuit affirmed, that the term "patient" could not encompass healthy individuals, and based on this, the court dedicated and excluded several embodiments including the simple exercise monitoring embodiment of the invention. Due to this "dedication" holding, only the most detailed embodiment of the patent remained undedicated.

In its ruling that was affirmed by the circuit court, the district court even refused to construe the claim term it was using to strip the patentee of her rights. Instead, the court simply reasoned that the term "patient" was in juxtaposition with other terms such

as "healthy individual" or "subject" in the written specification, without pointing to where such juxtaposition could be found. Indeed, examination of the patent specification showed to the contrary that there is no such juxtaposition and instead the patent used the words "patient" and "subject" and "subject" and "individual" interchangeably as explained above.

Therefore, the district court and the circuit court interpreted the term "patient" to always mean "sick," and despite the teachings of the patent and its claims, the fact that nothing equated "patient" with "sick," and contrary to the common meaning of the term, provided a claim construction which resulted in the dedication of most of the patentee's rights and exclusion of several embodiments of her patent including the most simple embodiment of the invention that was infringed by several defendants.

2. The Federal Circuit ruled against its own precedent in this case without providing any explanation.

The Federal Circuit has repeatedly ruled that a claim construction which excludes a preferred embodiment is rarely, if ever, correct. *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003); *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Such a construction "would require highly persuasive evidentiary support." *Id.* The ruling of the courts in this case did not even contain a full construction of the disputed term that was used to exclude and dedicate the patent

embodiments, let alone any highly persuasive evidence.

When a hearing of the case was held before the circuit judges in the appeal procedure, one of the panel judges, Judge Rader, was clearly against the notion that "patient" could not encompass a healthy person and asked one of the defendants:

> Why can't a patient be a healthy subject? I go to my doctor all the time, I'm rather healthy, he calls me his patient.

He further stated:

> I don't see anywhere here that the patent has defined patient to exclude a normal person. In fact, I think it is exactly the other way around. It has included within its claimed invention an embodiment that covers normal healthy people. So obviously, a patient is a normal healthy person too.

Audio recording of the hearing posted at: http://oralarguments.cafc.uscourts.gov/searchscript.asp

Despite the discussion at oral argument, the Federal Circuit affirmed the district court's ruling without any opinion or explanation several months later. Therefore, the Federal Circuit stripped the rights of a patentee in this case contrary to its own precedent, contrary to the discussion expressed during the hearing, and despite lack of any genuine justification.

3. The Federal Circuit ruling in this case disrupts the settled expectations of the inventing public.

This Court has repeatedly advised that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 28 (1997)). Not only is the decision by the Federal Circuit in this case erroneous as discussed above, but it also upsets the settled expectations of the inventing public and patentees and endangers innovation. If the inventors lose faith in the enforceability of patents, it is unlikely that they will continue to invest time and energy to develop new inventions. This will have a chilling effect on the ability of the patent system to foster innovation under the constitutional mandate "to promote the progress of ...useful arts." U.S. Const., art. I, § 8, cl. 8.

In sum, this case presents an opportunity for this Court to correct claim construction errors that result in the dedication of important patent rights. Without strong patent enforcement, there can be no incentive for research and innovation for inventors. *Chakrabarty,* 447 U.S. at 307.

It is also important that the Court grants this petition to show that the individual patentees' rights are not to be taken lightly, and when there is gross injustice and/or error against such a patentee, this court is prepared to act. Indeed, many major inventions that have placed the US at the forefront

of technology have been developed by individual inventors. There are many individual patentees in the United States who, like the Petitioner, have developed and continue to come up with new innovative techniques, relying on the patent protection they are assured to receive under the law. This is an opportunity for this Court to ensure that patent rights of individual inventors are not fading away.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

Fleur T. Tehrani,
Petitioner, *pro se*

United States Court of Appeals
for the Federal Circuit

2008-1135

FLEUR T. TEHRANI, PH.D.,

Plaintiff-Appellant,

v.

POLAR ELECTRO and POLAR ELECTRO OY,

Defendants-Appellees,

and

PHYSI-CAL ENTERPRISES,

Defendant,

and

CAT EYE CO., LTD.,

Defendant-Appellee.

William C. Rooklidge, Howrey LLP, of Irvine, California, argued for plaintiff-appellant. With him on the brief was Henry A. Petri, Jr., of Houston, Texas.

John P. Moran, Holland & Knight LLP, of Washington, DC, argued for defendants-appellees Polar Electro, et al. With him on the brief was Tamara F. Carmichael, of New York, New York.

Joseph M. Kuo, Olson & Cepuritis, Ltd., of Chicago, Illinois, argued for defendant-appellee Cat Eye Co., Ltd. With him on the brief were Seymour Rothstein and Matthew D. Kellam.

Appealed from: United States District Court for the Central District of California

Judge David O. Carter

NOTE: This disposition is nonprecedential.

Judgment

ON APPEAL from the United States District Court for the Central District of California

in CASE NO(S). 05-CV-1113 and 06-CV-20

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

Per Curiam (NEWMAN, RADER and PROST, *Circuit Judges*).

AFFIRMED. *See* Fed. Cir. R. 36.

ENTERED BY ORDER
OF THE COURT

DATED December 5, 2008 /s/ Jan Horbaly
Jan Horbaly, Clerk

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

FLEUR T. TEHRANI, Ph.D., **Plaintiff,** **v.** **POLAR ELECTRO, INC., et al.,** **Defendants.**	**CASE NO. SA CV 05-1113 DOC (FFMx)** ~~**SACV060020 DOC (RNBx)**~~ ***ORDER* RE CLAIM CONSTRUCTION AND CROSS MOTIONS FOR SUMMARY JUDGMENT**
FLEUR T. TEHRANI, Ph.D., **Plaintiff,** **v.** **CAT EYE CO., LTD., et al.,** **Defendants.**	(Filed Oct. 3, 2007) (Entered Oct. 4, 2007)

Before the Court are the following motions: (1) Plaintiff Fleur T. Tehrani, Ph.D's ("Dr. Tehrani" or "Plaintiff") Motion for Claim Construction; (2) Defendant Cat Eye Co., Ltd.'s ("Cat Eye") Motion for Claim Construction; (3) Defendant Physi-Cal Enterprises, Inc.'s ("Physi-Cal") Motion for Summary Judgment of Non-Infringement; (4) Defendants Polar Electro, Inc. and Polar Electro, Oy's (collectively "Polar") Motion for Summary Judgment; (5) Plaintiff's Motion for Summary Judgment of Infringement as to Defendants Polar and Physi-Cal; and (6) Cat Eye's Motion for Summary Judgment. After considering the moving, opposing, and replying papers, as well as oral

arguments, and construing the relevant claims, the Court hereby GRANTS Physi-Cal's Motion for Summary Judgment of Non-Infringement; GRANTS IN PART Polar's Motion for Summary Judgment; GRANTS IN PART Cat Eye's Motion for Summary Judgment; and DENIES Plaintiff's Motion for Summary Judgment of Infringement. Because these rulings dispose of the case, the Court does not address the remaining arguments about invalidity raised in Polar's and Cat Eye's Motions for Summary Judgment.[1]

I. BACKGROUND

Plaintiff Dr. Tehrani is a tenured professor at California State University, Fullerton. She holds a Ph.D. in electrical engineering with an emphasis on systems and control engineering and their applications in biological systems. Dr. Tehrani's main research area is biomedical engineering and she has a particular interest in the application of engineering methods in healthcare and medicine.

Defendant Polar Electro, Oy is a Finnish company that manufactures and sells heart rate monitor

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[1] Because the Court finds, as a matter of law, that the accused devices do not infringe the '259 Patent, any ruling on validity would be merely advisory. The Court accordingly stays Defendants' invalidity counterclaims and certifies its finding of non-infringement so that the case is in a proper posture for appeal. *See Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 829-30 (Fed. Cir. 2003).

watches and bicycle computers. Defendant Polar Electro, Inc. is Polar Electro, Oy's North American subsidiary, which imports and sells Polar products in the United States. Defendant Physi-Cal is a Canadian company, which sells heart rate monitor watches in the United States under the Mio brand name. Defendant Cat Eye is a Japanese company that imports and sells heart rate monitors and bicycle computers in the United States.

In 1988, Dr. Tehrani developed a method and apparatus for determining a patient's metabolic rate ratio ("MRR"), which purportedly improved upon the existing cumbersome or inaccurate metabolic rate monitors. She filed a patent application for this invention in April of 1989 and obtained a patent, United States Patent Number 4,909,259 ("the '259 Patent" or "the Patent"), on March 20, 1990. The '259 Patent is directed to an apparatus and method for determining a patient's MRR from the patient's oxygen and carbon dioxide concentrations and cardiac function. '259 Patent, Abstract, Ex. A to Decl. of Scott Maynard in Supp. of Dr. Tehrani's Opening Claim Construction Br. (hereinafter "Pl.'s Ex. A, Patent"). Cardiac function is defined as "either heart rate and stroke volume of the patient, or cardiac output data." *Id.* at Abstract. Cardiac output is the volume of blood ejected by the heart in a given period of time and stroke volume is the volume of blood ejected by the heart in a single beat, which yields cardiac output when multiplied by the heart rate. The '259 Patent expressly defines metabolic rate ratio ("MRR") as "the

ratio of metabolic rate to basal rate of metabolism." '259 Patent, Col. 1, lns. 57-58. "Metabolism" is the energy used in an activity and "metabolic rate" is the rate at which a person expends energy. "Basal rate of metabolism" is the rate at which a person expends energy at complete rest after fasting, i.e. a period of 12 hours rest and without food or caffeine; "basal metabolism" is the energy used by a body for its most essential activities such as breathing, maintaining membrane potentials and resting levels of neural, cardiac, liver and kidney function.

MRR was not a novel concept to the '259 Patent – it had been know for decades, more commonly as Metabolic Equivalents ("METS"). Moreover, as the '259 Patent acknowledges, prior art had previously recognized the relationship between metabolic rate and oxygen uptake and devices already existed to measure oxygen uptake as indicative of metabolic rate. However, citing a number of pitfalls with using oxygen uptake as an indicator of metabolic rate, the '259 Patent set out to create a new method and apparatus for measuring MRR based upon a discovery of the relationship between MRR and a patient's cardiac output and certain blood gas levels. According to the '259 Patent, the invention was based on Dr. Tehrani's finding that "a patient's metabolic rate ratio (MRR) can be reliably determined under both steady state and transient conditions without measuring oxygen uptake by employing data indicative of the patient's carbon dioxide and oxygen pressures of arterial blood and the patient's cardiac output." *Id.* at Col. 1, lns.

51-57. In particular, the findings that "cardiac output increases rapidly and enormously as the MRR increases, and cardiac output increases as arterial CO_2 [carbon dioxide] pressure increases and as arterial O_2 [oxygen] pressure decreases." *Id.* at Col. 2, lns. 9-13.

The '259 Patent describes in detail the particular apparatus for obtaining individuals' MRR and provides two distinct embodiments for the apparatus. One of these embodiments is taught for a "patient." *Id. passim.* The other, referenced twice as a simplified version of the "patient" embodiment, is for "a normal healthy subject" or "normal, healthy individuals." *Id.* at Col. 5, lns. 3-8; Col. 9 lns. 7-13. Despite the disclosure of different apparatuses for different classes of individuals, the claims at issue are specific to the "patient" apparatus. None of the claims are directed to the embodiment for "normal, healthy individuals," "normal healthy subjects" or any other generic term that could encompass both patients and normal, healthy individuals, such as "individual," "subject," or "person."

On November 14, 2005, Dr. Tehrani filed suit against Defendants Polar and Physi-Cal ("the Polar matter"), alleging that several of their products infringe the '259 Patent. On January 9, 2006, Dr. Tehrani filed a second case against multiple defendants, including Cat Eye ("the Cat Eye matter"), likewise alleging that several of their products infringe the '259 Patent. Given the significant over lap between these related cases, upon Polar and

Physi-Cal's motion, the Court consolidated the Polar and Cat Eye matters on June 19, 2007.

Discovery is complete in both cases. The parties now move the Court for an order construing the asserted claims of the '259 Patent. The parties also move for summary judgment: Polar and Cat Eye as to invalidity and non-infringement; Physi-Cal as to non-infringement; and Dr. Tehrani as to infringement against Polar and Physi-Cal.

II. CLAIM CONSTRUCTION

Patent infringement analysis involves two steps: (1) an interpretation of the asserted claims, and (2) a comparison of the claims to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996). Claim interpretation is a matter of law, *Markman*, 52 F.3d at 979, and is thus amenable to summary judgment, even though the analysis involves both issues of law and questions of fact. *Phonometrics Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1463-64 (Fed. Cir. 1998). Many courts, however, have chosen to hold a claim interpretation hearing, or *Markman* hearing, to facilitate the claim interpretation process. *See e.g., Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1577 (Fed. Cir. 1996).

Claim interpretation begins with the language of the claim. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). Terms in the claim

are generally given the ordinary and customary meaning they would have to a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). However, the terms must be read in the context of the entire patent. *Id.* at 1314. In interpreting the claims, the court focuses primarily on the intrinsic evidence of record, including the claims themselves, the specification, and if in evidence, the prosecution history. *Id* at 1312-17.

Among the intrinsic evidence, the specification is always highly relevant to the claim construction analysis – it is the single best guide to the meaning of a disputed term, and is usually dispositive. *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996))."The specification is, thus, the primary basis for construing the claims." *Id.* (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)). In addition to the specification, the court will also consider the prosecution history, consisting of "the complete record" of the patent. *Id.* at 1317. However, because the prosecution history often lacks the clarity of the specification, it is less useful for claim interpretation purposes. *Id.*

While the court may also consider extrinsic evidence, including expert testimony, dictionaries, and learned treatises, as the Federal Circuit has recently made clear, such evidence is generally viewed as less reliable than intrinsic evidence. *Phillips,* 415 F.3d at 1317-18. Therefore, the court must use its discretion in admitting and weighing extrinsic

evidence, keeping in mind its inherent flaws. *Id.* at 1319.

As to Defendants Polar and Physi-Cal, Dr. Tehrani is asserting Claims 1, 6, and 8 of the '259 Patent. As to Defendant Cat Eye, Dr. Tehrani is asserting Claims 1, 6, 7, and 8 of the '259 Patent. Claims 6 through 8 are dependent claims and thus, the only independent claim asserted in this action is Claim 1, which reads:

> Apparatus comprising:
>
> (a) first means for providing data indicative of a cardiac function of a patient; and
>
> (b) second means for determining the patient's metabolic rate ratio based upon the data provided by the first means.

'259 Patent 11:4-9. Claim 6 reads "Apparatus according to claim 1 wherein the first means comprises a heart monitor." '259 Patent 11:38-39. Claim 7 reads "Apparatus according to claim 6 wherein the heart rate monitor comprises a pulse monitor for providing a systolic pulse signal." '259 Patent 11:40-42. Claim 8 reads "Apparatus according to claim 6 wherein the heart rate monitor comprises means for processing an ECG signal." '259 Patent 11:43-45.

The parties dispute the proper construction of both the "first means" and the "second means" of Claim 1, as well as the meaning of the terms "cardiac function" and "patient." As to the term "patient," the Court agrees with Polar and Physi-Cal that it need

not be explicitly defined, except to note that because of the term's juxtaposition with the contrasting "normal, healthy individual," regardless of its exact definition, the term "patient" in the '259 Patent indicates something other than a "normal, healthy individual."[2]

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[2] Even were the Court to accept Dr. Tehrani's invitation to define the term "patient," the Court would not adopt her proposed "rare" linguistic definition: "a person or thing that undergoes some action." Ex. A to Decl. of Scott Maynard in Opp'n to Defs.' Opening Markman Br. at 6 (Webster's Encyclopedic Unabridged Dictionary entry labeling this secondary definition as "rare"); Ex. 7 to Decl. of Joseph M. Kuo in Opp'n to Pl.'s Mot. for Claim Construction ("Kuo Opp'n Claim Decl.") (in linguistics, "patient" is the noun in a sentence that is acted upon by the verb; e.g. in the sentence "she threw the ball," "ball" is the patient). Instead, the Court would adopt the common and primary definition of "patient": "a person who is under medical or surgical treatment" for several reasons. *Id.* First, the medical treatment definition is logical, whereas the linguistic definition is irrelevant, in the context of the '259 Patent, pertaining to medical or health related applications. Second, this medical treatment definition makes sense in the context of the '259 Patent's explicit contrast between the "patient" embodiment and the "normal, healthy individual" embodiment. Finally, the specification shows that patient and subject are not used as synonyms in the '259 Patent because "subject" refers to either a "patient" or a "normal, healthy individual," whereas "patient" refers to something other than a "normal, healthy individual." '259 Patent 5:30-39; 9:7-13.

A. Claim 1: "First Means for providing data indicative of a cardiac function of a patient"

The parties agree that the "first means" is a means-plus-function claim subject to 35 U.S.C. §112, ¶6.[3] This requires "both identification of the claimed function and identification of the structure in the written description necessary to perform that function." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

In a literal infringement analysis, the court must first interpret the asserted claims to determine their meaning and scope, and then determine whether the claims read on the accused product. *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Id.* Additionally, an examination of a means-plus-function claim is guided by section 112 of the Patent Act. Because a literal reading of means-plus-function language "could encompass any conceivable means for performing the function," the court must

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[3] An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. §112, ¶6.

construe the patent in light of the patent specification. *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042 (Fed. Cir. 1993). This limits patent protection to the invention specified in the patent and its equivalent. *Id.* Thus, "for a means-plus-function limitation to read on an accused device, the accused device must employ means identical to or the equivalent of the structures, material, or acts described in the patent specification. The accused device must also perform the identical function as specified in the claims." *Id.*

Cat Eye contends that the function of the "first means" is evident from the language of Claim 1, namely the first means must "provide data indicative of a cardiac function *of a patient.*" '259 Patent 11:5-6 (emphasis added); *accord Creo Prods. v. Presstek, Inc.*, 305 F.3d 1337, 1344 (Fed. Cir. 2002) ("function of a means-plus-function limitation . . . must come from the claim language itself). The Court agrees and looks to the specification for guidance as to the definition of the "cardiac function of a patient." *See Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1360 (Fed. Cir. 2005) ("the specification necessarily informs the proper construction of the claims and it is appropriate for a court . . . to rely heavily on the written description for guidance as to the meaning of claims") (internal quotations omitted).

The '259 Patent discloses two apparatus embodiments, one of which is specific to a patient. This patient embodiment is the main focus of the specification and includes CO_2 and O_2 blood gas sensors, as well as either a cardiac output monitor or stroke

volume and heart rate monitors. '259 Patent *passim*; *see also* Polar, Physi-Cal Defs.' Opening Markman Br. at 7:22-10:11 (listing examples of the numerous locations in the '259 Patent where the term "patient" is used to describe the apparatus and method). The other embodiment is for "normal, healthy individuals." Unlike the patient embodiment, the apparatus for a "normal, healthy individual" does not use blood gas sensors. The normal healthy individual embodiment is discussed only twice in the specification, both times as a potential simplified version of the patient embodiment. *See* Pl.'s Ex. A, Patent Col. 5, lns. 3-8, Col. 9, lns. 7-13. Given this disclosure, if Claim 1 claimed an apparatus comprising first means for providing data indicative of the cardiac function of a subject, an individual, a person, or some other generic term, Claim 1 would cover both embodiments disclosed in the specification. The problem is that Dr. Tehrani did not employ such generic terms, instead she chose to limit each of the claims at issue to the cardiac function of a "patient." Therefore, because Dr. Tehrani did not claim the disclosed simplified "normal, healthy individual" embodiment, it is dedicated to the public. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106 (Fed. Cir. 1996) (reiterating well-established rule that "subject matter disclosed but not claimed in a patent application is dedicated to the public"). As the patentee, Dr. Tehrani was free to choose the words of her claims, her failure to claim the "normal, healthy individual" embodiment is her responsibility.

See Sage Prods. v. Devon Indus., 126 F.3d 1420, 1425 (Fed. Cir. 1997) ("as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure"). She cannot retroactively contort the intrinsic evidence to attempt to cover an embodiment she failed to claim in her '259 Patent. Moreover, Dr. Tehrani explicitly describes her "invention" as the patient embodiment: "The present invention relates to a method and apparatus for determining a patient's MRR using data indicative of CO_2 (carbon dioxide) and O_2 (oxygen) pressures of the patient's arterial blood and of the patient's cardiac output." '259 Patent 2:5-9. Accordingly, the Court looks to the patient apparatus disclosed in the '259 Patent to determine the structure for the claimed elements.

The disclosed structure for the first means requires a device for supplying data indicative of a cardiac function. Thus, the next step in construing "first means" is determining the meaning of the term "cardiac function." Because Dr. Tehrani "is not entitled to a claim construction divorced from the context of the written description," *Nystrom v. Trex Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005), the Court declines Dr. Tehrani's invitation to begin the investigation with general purpose dictionary definitions for "cardiac" and "function." *See* Pl.'s Opening Claim Construction Br. 8:8-9:2 (combining definitions of cardiac and function to define cardiac function). Dr. Tehrani's

resort to the separate dictionary definition of each word, shows that at the time the '259 Patent was filed, the claim term "cardiac function" had no commonly understood meaning. Similarly, notable extrinsic sources show no accepted definition in the relevant art – neither *Dorland's Medical Dictionary,* nor the book entitled, *Physiology and Biophysics,* which Dr. Tehrani relied upon in preparing her doctoral thesis, define "cardiac function." Exs. 2, 3 to Kuo Opp'n Claim Decl. Moreover, simply combining the definitions of "cardiac" and "function" results in a broad, vague definition that is untenable in light of the specification.[4] *Network Commerce, Inc.,* 422 F.3d at 1360 (rejecting similar invitation to define "download component" by combining individual definitions of "download" and "component").

The Court, therefore, looks to the '259 Patent, which itself explicitly defines the term "cardiac function."[5] "[C]ardiac function data may be either

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[4] Dr. Tehrani's proposed definition of "function" is any action of an organ, such that cardiac function data would be "data indicative of the physiological activity of the heart." This definition would encompass creating and maintaining blood pressure; however, blood pressure, like heart rate alone, is not taught to be "cardiac function" data in the '259 Patent.

[5] There is no justification for turning to the dictionary here, since the '259 Patent explicitly defines the disputed term, whereas in *Network Commerce* the specification did not use the disputed term; nevertheless, even in that situation, the Federal Circuit looked to the specification for the term that "corresponds most closely to the [claimed term]" instead of combining dictionary definitions. *Network Commerce, Inc.,* 422 F.3d at 1360.

heart rate and stroke volume of the patient, or cardiac output data." Pl.'s Ex. A, '259 Patent, Abstract; *W.E. Hall Co. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1350 (Fed. Cir. 2004) ("While dictionaries may be used to ascertain the plain and ordinary meaning of claim terms, the intrinsic record is used to resolve ambiguity in claim language or, where it is clear, trump inconsistent dictionary definitions."). Dr. Tehrani argues that the use of the word "may" in the Abstract's definition indicates that what follows are simply two acceptable types of cardiac function, but that cardiac function is not clearly limited to these two types. Dr. Tehrani's reliance on the word "may," however, is misplaced because the "may" is followed by an "either or" clause. Thus, the may merely indicates that cardiac function can be either of the following two things: "heart rate and stroke volume" or "cardiac output data." '259 Patent Abstract. The Summary of Invention section further supports the Abstract definition that cardiac function is either heart rate and stroke volume or cardiac output data:

> Cardiac output data may be obtained in at least one of two methods. [¶] In a first method, data indicative of the patient's heart rate and stroke volume is provided and the patient's cardiac output is computed therefrom . . . [¶] In a second method, data indicative of the patient's cardiac output is directly provided by a cardiac output monitor.

'259 Patent 2:19-38. This explicit teaching in the '259 Patent similarly defeats Dr. Tehrani's unsupported

assertion that the Abstract merely lists examples of cardiac function. Moreover, the '259 Patent does not merely discuss cardiac output as part of the preferred embodiment, rather the Patent teaches that such data is an integral part of the invention. In fact, the invention itself is based upon Dr. Tehrani's finding about the relationship between cardiac output and carbon dioxide and oxygen pressures of arterial blood; in particular, the findings that "cardiac output increases rapidly and enormously as the MRR increases, and cardiac output increases as arterial CO_2 [carbon dioxide] pressure increases and as arterial O_2 [oxygen] pressure decreases." *Id.* 2:9-13.

> The present invention is based upon the inventor's finding that a patient's metabolic rate ratio (MRR) can be reliably determined under both steady state and transient conditions without measuring oxygen uptake by employing data indicative of the patient's carbon dioxide and oxygen pressures of arterial blood and the patient's cardiac output.

Id. 1:51-57. In light of the intrinsic evidence defining "cardiac function" as "cardiac output" or "heart rate and stroke volume," it would be improper to allow Dr. Tehrani to redefine and broaden the term "cardiac function" in the '259 Patent for purposes of this litigation based on extrinsic evidence.

> In the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public – i.e., those of ordinary skill in the art – that the

> inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.

Nystrom, 424 F.3d at 1145. Nothing in the '259 Patent's definition indicates that cardiac function as the term is used in the '259 Patent can be anything other than a patient's "heart rate and stroke volume" or "cardiac output data." Accordingly, the fact that after filing her motion for claim construction, Dr. Tehrani found a *Mechanical Ventilation* textbook with a section entitled "terms specific to cardiac function"[6] does not alter the '259 Patent's narrower cardiac function definition, nor does it supplement the lack of requisite notice to the public in the '259 Patent that Dr. Tehrani intended the disputed term to encompass this broader textbook definition. In addition, given that heart rate multiplied by stroke volume results in cardiac output, the Court agrees with Defendants that "cardiac function" means "cardiac output." Thus, "cardiac function" is either "heart rate and stroke volume" or "cardiac output," i.e. the amount of the

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[6] There are several terms used frequently during hemodynamic monitoring. These include: heart rate, pulse pressure, stroke volume, cardiac output, cardiac index, preload, contractility, afterload, and vascular resistance." Ex. A to Decl. of Scott Maynard in Supp. of Pl's Opp'n to Cat Eye's Mot. for Claim Construction at A-10.

heart's blood output in a given period of time. Thus, the data provided by the first means is cardiac output data.

Dr. Tehrani also seeks to use the doctrine of claim differentiation to support her interpretation of "cardiac function," arguing that Claims 9 and 10, which depend from Claim 1 would be rendered superfluous if Claim 1 is construed to require either stroke volume and heart rate or cardiac output. Pl.'s Opp'n to Cat Eye's Mot. for Claim Construction 3:20-25. First, on its face, this claim differentiation argument fails to defeat the Court's construction that cardiac function is either heart rate and stroke volume or cardiac output because under this interpretation, Claims 9 and 10's limitations are not superfluous, but rather dictate which type of structure supplies the cardiac function data. Specifically, Claim 9 requires that the first means include a stroke volume monitor (in addition to the heart rate monitor required by Claim 6 from which Claim 9 depends), whereas Claim 10 requires that the first means include a cardiac output monitor. Because Claim 1 permits either type of monitor (cardiac output or stroke volume plus heart rate), Claims 9 and 10 add limitations by dictating the specific type of monitor used to obtain the cardiac function data.

In addition, the doctrine of claim differentiation merely provides a presumption that different claims are of different scope. *Tandon Corp. v. United States Int'l Trade Comm'n,* 831 F.2d 1017, 1023-24 (Fed. Cir. 1987). Describing claim elements or limitations in

different words, however, does not invariably alter the scope of the claim. *Id.*; *see also Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) (claims "written in different words may ultimately cover substantially the same subject matter"). "[T]he written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation." *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000). Claim differentiation is not a "hard and fast rule of construction, and cannot be relied upon to broaden claims beyond their correct scope." *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) (internal quotations omitted); *accord Tandon Corp.*, 831 F.2d at 1024 ("Whether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed"). Here, the intrinsic evidence supporting the interpretation that cardiac function is cardiac output or heart rate and stroke volume trumps any presumptions that may arise from the doctrine of claim differentiation.

Basic terminology employed in various claims of the '259 Patent further highlights the flaws in Dr. Tehrani's argument. First, Claim 6's use of the term "comprises" ("first means *comprises* a heart monitor") indicates merely that the first means includes at least a heart rate monitor. The word "comprise" is a term of art in patent law indicating that the claim is "inclusive or open-ended and does not exclude additional, unrecited elements or method steps." *Georgia-Pacific*

Corp. v. United States Gypsum Co., 195 F.3d 1322, 1327 (Fed. Cir. 1999). "A drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially more.'" *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000). Accordingly, Claim 6 merely states that the first means includes at least a heart rate monitor.

Additionally, Dr. Tehrani's argument that the "a" modifying "cardiac function" in the first means of Claim 1 indicates that only the single function of heart rate is needed is similarly misguided. As the Federal Circuit "has repeatedly emphasized," the "indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). Therefore, "[u]nless the claim is specific as to the number of elements, the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." *Id.* Nothing in the '259 Patent indicates an intent to so limit the article. In fact, the possibility of more than one kind of cardiac function data is found in the teaching that "cardiac function" can be data from heart rate and stroke volume monitors. Accordingly, the conventional rule applies that "the claim limitation 'a,' without more, requires at least one." *Id.* In every embodiment, cardiac output is used; when a cardiac output monitor is not used, devices for providing the patient's stroke volume and heart rate are taught so that cardiac output can be

calculated. The sole teaching in the '259 Patent where only a single "cardiac function" is used is with cardiac output. Thus, even where the patient embodiment utilizes a single cardiac function, that function is cardiac output, not heart rate.

As to the corresponding structure, the '259 Patent teaches that cardiac output is either measured by a cardiac output monitor or computed from heart rate and stroke volume, in which case stroke volume is measured via a stroke volume monitor either continuously or prior to operation of the system[7] and heart rate is measured via a heart rate monitor. Thus, the structures disclosed in the '259 Patent for obtaining cardiac function data are (1) a cardiac output monitor or (2) a heart rate monitor in combination with a stroke volume monitor, whereby cardiac output is calculated by multiplying heart rate by stroke volume.

Finally, given that the first means is properly limited to a structure that provides a patient's cardiac output, the first means also includes sensors for

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[7] Even though stroke volume need not be continuously monitored in one preferred embodiment of the invention, the '259 Patent still requires that stroke volume be "obtained from the patient prior to operation of the system" and input as a constant '259 Patent 5:43-48. Thus, while stroke volume can be input as a constant, there is no teaching or claim in the Patent permitting a generic representative value for stroke volume to be used in lieu of the patient's actual stroke volume. Thus, regardless of when and how stroke volume is monitored, in all embodiments, it is obtained from the patient, i.e. measured.

monitoring blood gas pressures because the '259 Patent teaches that the CO_2 and O_2 pressures are factors that contribute to a patient's cardiac output. Moreover, in every variation of the patient apparatus, the first means includes a structure for supplying the cardiac output of a patient, which includes the effects of CO_2 and O_2 blood gas pressures. Even Dr. Tehrani acknowledges that it is necessary to have blood gas monitors with the embodiment for a nonhealthy subject, i.e. a patient. Dep. of Fleur Tehrani, Ex. 4 to Kuo Opp'n Claim Decl.

The Court therefore adopts Defendants proposed construction of the first means of Claim 1: "the structure to provide the data used by the equations 1-9 of the '259 Patent, which must include sensors to measure the patient's arterial CO_2 and O_2 gas pressures and either a heart rate monitor and data representative of stroke volume or a cardiac output monitor."

Given that the proper construction of the first means of Claim 1 resolves the issue of infringement, the Court need not construe the other disputed claims.

III. SUMMARY JUDGMENT

A. LEGAL STANDARD

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact

and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

The Court must view the facts and draw inferences in the manner most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S. Ct. 993 (1962); *Chevron Corp. v. Pennzoil Co.*, 974 F.2d 1156, 1161 (9th Cir. 1992). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial, but it need not disprove the other party's case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S. Ct. 2505 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S. Ct. 2548 (1986). When the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by pointing out the absence of evidence of a genuine issue of material fact from the non-moving party. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 806-07 (Fed. Cir. 1999).

Once the moving party meets its burden, the "adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party." Fed. R. Civ. P. 56(e); *see also Anderson*, 477 U.S. at 248-49. Furthermore, a party cannot create a genuine issue of material fact simply by making assertions in its legal papers. There must be

specific, admissible evidence identifying the basis for the dispute. *S.A. Empresa de Viacao Aerea Rio Grandense v. Walter Kidde & Co., Inc.*, 690 F.2d 1235, 1238 (9th Cir. 1980). The Supreme Court has held that "[t]he mere existence of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for [the opposing party]." *Anderson*, 477 U.S. at 252.

B. NON-INFRINGEMENT

After interpreting the asserted claims to determine their meaning and scope, a court performing a literal infringement analysis must determine whether those claims read on the accused product. *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Id.* In particular, "[l]iteral infringement of a means-plus-function claim requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308 (Fed. Cir. 2003). Because Claim 1 is the only independent claim asserted, it provides the broadest patent protection possible and is thus the focus of Defendants' assertion of non-infringement.

"A determination of infringement, both literal and under the doctrine of equivalents, is a question of

fact." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001). However, the question of infringement becomes a question of law where the parties do not dispute any relevant facts regarding the structure or composition of the accused device. *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996). "Thus, a literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Bai v. L & L Wings,* 160 F.3d 1350, 1353 (Fed. Cir. 1998). In this case, the parties do not dispute the relevant facts about the accused devices. Instead, their dispute centers around the proper claim construction. Thus, now that the Court has construed the first means of Claim 1, infringement can be determined as a matter of law.

It is undisputed that Defendants Polar, Physi-Cal, and Cat Eye's accused devices only measure heart rate. The accused devices, therefore, do not perform the identical function as the first means of Claim 1 in the '259 Patent because the devices do not provide cardiac function data, i.e. cardiac output (measured or calculated with stroke volume) and blood gas levels. *See IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430 (Fed. Cir. 2000) (identical function must be performed to reach next step of infringement analysis, i.e. determining whether accused device uses the same structure or equivalents).

Claims 6-8 depend from Claim 1. Because the alleged devices do not infringe Claim 1, they therefore cannot infringe Claims 6-8. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim").

Consequently, none of the accused devices infringe Dr. Tehrani's '259 Patent as a matter of law.

C. VALIDITY

To the extent Polar's and Cat Eye's Motions seek summary judgment on the grounds of the '259 Patent's alleged invalidity, the Motions are DENIED as moot since the Court need not reach this issue in light of its non-infringement ruling.

IV. DISPOSITION

For the reasons set forth above, (1) Physi-Cal's Motion for Summary Judgment of Non-Infringement is hereby GRANTED; (2) Polar's Motion for Summary Judgment is hereby GRANTED on the grounds of Non-Infringement; (3) Cat Eye's Motion for Summary Judgment is hereby GRANTED on the grounds of Non-Infringement; and Plaintiff's Motion for Summary Judgment of Infringement is hereby DENIED. The Court hereby STAYS Defendants' invalidity counterclaims and CERTIFIES its finding of non-infringement pursuant to Fed. R. Civ. P. 54(b).

IT IS SO ORDERED.
DATED: October 3, 2007

/s/ David O. Carter
DAVID O. CARTER
United States District
Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Date: October 4, 2007

Case No. SA CV 05-1113 DOC (FFMx)
[Consolidated with SA CV 06-20 DOC (RNBx)]

Title: FLEUR TEHRANI v. POLAR ELECTRO OY, et al.

DOCKET ENTRY

[I hereby certify that this document was served by first class mail or Government messenger service, postage prepaid, to all counsel (or parties) at their respective most recent address of record in this action on this date]

Date: _____ Deputy Clerk: _____

PRESENT:

THE HONORABLE DAVID O. CARTER, JUDGE

Kristee Hopkins	Not Present
Courtroom Clerk	Court Reporter
ATTORNEYS PRESENT FOR PLAINTIFFS:	ATTORNEYS PRESENT FOR DEFENDANTS:
NONE PRESENT	NONE PRESENT

PROCEEDING (IN CHAMBERS): ORDER CLARIFYING COUNTERCLAIMS STAYED IN COURT'S OCTOBER 3, 2007 ORDER

Page 18, lines 1-2 of the Court's October 3, 2007 Order re Claim Construction and Cross Motions for Summary Judgment is hereby AMENDED to read "The Court hereby STAYS Defendants' invalidity and inequitable conduct counterclaims and CERTIFIES its finding of non-infringement pursuant to Fed. R. Civ. P. 54(b)."

The Clerk shall serve this minute order on all parties to the action.

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Initials of Deputy Clerk
KH

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IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

FLEUR T. TEHRANI, Ph.D., an individual Plaintiff, vs. CAT EYE CO., LTD. et al. Defendants.	Case No. SACV06-20-DOC (RNBx) **DECLARATION OF SCOTT R. MAYNARD IN SUPPORT OF DR. TEHRANI'S OPPOSITION TO CAT EYE'S MOTION FOR CLAIM CONSTRUCTION** **Judge:** **Hon. David O. Carter** **Date:** **June 25, 2007** **Time:** **8:30 a.m.** **Courtroom:** **9D** Fact Disc. Cut-Off: Feb. 28, 2007 Expert Disc. Cut-Off: June 1, 2007 Pretrial Conf.: Sept. 24, 2007 Trial: Oct. 9, 2007 **JURY DEMAND**

Executed on June 11, 2007, at Irvine, California.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ Scott R. Maynard
Scott R. Maynard

Susan P. Pilbeam, M.S., R.R.T., Mechanical Ventilation: Physiological and Clinical Applications (2d ed. 1992)

* * *

[433] valves in the heart are again closed (Fig 11-1,C), the heart continues to relax. Blood volume in the heart does not change. Thus, it is called the isovolumetric relaxation phase.

Rapid Ventricular Filling. – While the ventricles were in systole, blood was still returning to the heart from the veins. This blood was entering and filling the atria while these other events were taking place. This rise in blood volume in the atria is marked by the v wave on the atrial pressure tracing. Eventually, the pressure from this build-up of atrial blood exceeds the pressure in the now "relaxed" ventricles. This results in the opening of the cuspid valves and blood falls from the atria into the ventricles. This marks a period of rapid filling of the ventricles. This accounts for 60% to 80% of the blood volume in the ventricles.

Reduced Ventricular Filling. – As diastole continues, blood continues to return to the heart and pass through the atria and into the ventricles.

Summary. – These events occur in the right and left heart simultaneously. The pressure waveforms from these phases are identical in both the right and left atria, the right and left ventricles, and the pulmonary artery and aorta. The only difference is in the amount of pressure generated in the right heart compared to the left heart (Table 11-1).

Terms Specific to Cardiac Function

There are several terms used frequently during hemodynamic monitoring. These include: heart rate, pulse pressure, stroke volume, cardiac output, cardiac index, preload, contractility, afterload, and vascular resistance. These are briefly reviewed below.

TABLE 11-1.
Normal Pressures in the Right and Left Heart

Site	Pressure (mm Hg)
Right atrial pressure	3-6
Right ventricular diastolic pressure	0-6
Right ventricular systolic pressure	15-25
Pulmonary artery pressure	Diastolic 10-15 Systolic 15-25
Left atrial pressure	3-8
Left ventricular diastolic pressure	0-8
Left ventricular systolic pressure	90-140
Systemic arterial pressure	Diastolic 60-90 Systolic 90-140

* * *

The Random House Dictionary of the English Language (2d ed. unabr. 1987)

* * *

[1421] **pa·tient** (pā′shant), *n.* **1.** a person who is under medical care or treatment. **2.** a person or thing that undergoes some action. **3.** *Archaic* a sufferer or victim. —*adj.* **4.** bearing provocation, annoyance, misfortune, delay, hardship, pain, etc., with fortitude and calm and without complaint, anger, or the like. **5.** characterized by or expressing such a quality: *a patient smile.* **6.** quietly and steadily persevering or diligent, esp. in detail or exactness: *a patient worker.* **7.** undergoing the action of another (opposed to *agent*). **8. patient of. a.** having or showing the capacity for endurance: *a man patient of distractions.* **b.** susceptible of: *This statement is patient of criticism.* [1275-1325; ME *pacient* (adj. and n.) < MF < L *patient-* (s. of *patiēns*), prp. of *patī* to undergo, suffer, bear; see -ENT] —**pa′tient·less**, *adj.* —**pa′tient·ly,** *adv.* —**pa′tient·ness,** *n.*

—**Syn. 1.** invalid. **4.** uncomplaining, long-suffering, forbearing, resigned, passive, calm. **5.** quiet, serene, unruffled, unexcited, self-possessed, composed. **6.** sedulous, assiduous, untiring. —**Ant. 4.** hostile. **5.** impatient, agitated.

The Random House Dictionary of the English Language (2d ed.) (unabridged) (1987)

* * *

[1893] **sub·ject** (*n., adj.* sub′jikt; *v.* səb·jekt′), *n.* **1.** that which forms a basic matter of thought, discussion, investigation, etc.: *a subject of conversation.* **2.** a branch of knowledge as a course of study: *He studied four subjects in his first year at college.* **3.** a motive, cause, or ground: *a subject for complaint.* **4.** the theme of a sermon, book, story, etc. **5.** the principal melodic motif *or* phrase in a musical composition, esp. in a fugue. **6.** an object, scene, incident, etc., chosen by an artist for representation, or as represented in art. **7.** a person who is under the dominion or rule of a sovereign. **8.** a person who owes allegiance to a government and lives under its protection: *four subjects of Sweden.* **9.** *Gram.* (in English and many other languages) a syntactic unit that functions as one of the two main constituents of a simple sentence, the other being the predicate, and that consists of a noun, noun phrase, or noun substitute which often refers to the one performing the action or being in the state expressed by the predicate, as *He* in *He gave notice.* **10.** a person or thing that undergoes or may undergo some action: *As a dissenter, he found himself the subject of the group's animosity.* **11.** a person or thing under the control or influence of another. **12.** a person as an object of medical, surgical, or psychological treatment or experiment. **13.** a cadaver used for dissection. **14.** *Logic.* that term of a proposition concerning which the predicate is affirmed or denied. **15.** *Philos.* **a.** that

which thinks, feels, perceives, intends, etc., as contrasted with the objects of thought, feeling, etc. **b.** the self or ego. **16.** *Metaphysics.* that in which qualities or attributes inhere; substance.

—*adj.* **17.** being under domination, control, or influence (often fol. by to). **18.** being under dominion, rule, or authority, as of a sovereign, state, or some governing power; owing allegiance or obedience (often fol. by *to*). **19.** open or exposed (usually fol. by *to*): *subject to ridicule.* **20.** being dependent or conditional upon something (usually fol. by *to*): *His consent is subject to your approval.* **21.** being under the necessity of undergoing something (usually fol. by *to*): *All beings are subject to death.* **22.** liable; prone (usually fol. by *to*): *subject to headaches.*

—*v.t.* **23.** to bring under domination, control, or influence (usually fol. by *to*). **24.** to bring under dominion, rule, or authority, as of a conqueror or a governing power (usually fol. by *to*). **25.** to cause to undergo the action of something specified; expose (usually fol. by *to*): *to subject metal to intense heat.* **26.** to make liable or vulnerable; lay open; expose (usually fol. by *to*): *to subject oneself to ridicule.* **27.** *Obs.* to place beneath something; make subjacent. [1275-1325; (adj.) < L *subjectus* placed beneath, inferior, open to inspection, orig. ptp. of *subicere* to throw or place beneath, make subject, equiv. to *sub-* *sum-* + *-jec-*, comb. form of *jacere* to throw + *-tus* ptp. suffix; r. ME *suget* < OF < L, as above; (n.) < LL *subjectum* grammatical or dialectical subject, n. use of neut. of *subjectus*; r. ME *suget*, as above; (v.) < L *subjectāre*, freq. of

subicere; r. ME *suget(t)en* < OF *sugetter* < L, as above] —**sub·ject´a·ble**, *adj.* —**sub·ject´a·bil´i·ty**, *n.* —**sub·ject´ed·ly**, *adv.* —**sub·ject´ed·ness**, *n.* —**sub´ject·less**, *adj.* —**sub´ject·like´**, *adj.*

—**Syn. 1. 4.** SUBJECT, THEME, TOPIC are often interchangeable to express the material being considered in a speech or written composition. SUBJECT is a broad word for whatever is treated in writing, speech, art, etc.: *the subject for discussion.* THEME and TOPIC are usually narrower and apply to some limited or specific part of a general subject. A THEME is often the underlying conception of a discourse or composition, perhaps not put into words but easily recognizable: *The theme of a need for reform runs throughout her work.* A TOPIC is the statement of what is to be treated in a section of a composition: *The topic is treated fully in this section.* **3.** reason, rationale. **17.** subordinate, subservient. **20.** contingent.

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FLEUR T. TEHRANI, Ph.D.

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

FLEUR T. TEHRANI, Ph.D., an Individual Plaintiff, vs. POLAR ELECTRO INC., OREGON SCIENTIFIC, INC. and PHYSI-CAL ENTERPRISES, Defendants.	Case No. SACV 05-1113 DOC (FFMx) **DECLARATION OF FLEUR T. TEHRANI Ph.D. IN SUPPORT OF THE REPLY TO HER MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT** **Judge: Hon. David O. Carter** **Date: May 21, 2007** **Time: 8:30 a.m.** **Place: Courtroom 9D** Fact Disc. Cutoff: Oct. 30, 2006

) Expert. Disc. Cutoff:
) Mar. 16, 2007
) Pretrial Conf. Date:
) Jun. 25, 2007
) Trial Date:
) Jul. 10, 2007
)
) **JURY DEMAND**

I declare under penalty of perjury of the laws of the United States, that the foregoing is true and correct.

Executed on May 09, 2007 in Irvine, California

/s/ F. T. Tehrani
Fleur T. Tehrani

Webster's New 20th Century Dictionary
(2nd ed) (1983)

* * *

[273] **cär´di·ac**, *a.* [L. *cardiacus*; Gr. *kardiokos*. pertaining to the heart; *kardia*, the heart.]

1. pertaining to the heart.
2. near the heart.
3. relating to the upper part of the stomach.

* * *

[741] **fuñç´tion**, *n.* [OFr. (Fr. *fonction*); L. *functio.*, from pp. of *fungi*, to perform.]

1. the normal or characteristic action of anything; especially, any of the natural, specialized actions of an organ or part of an animal or plant; as the procreative *function*.

* * *

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(2)

IN THE

Supreme Court Of The United States

FLEUR T. TEHRANI,
Petitioner,

v.

POLAR ELECTRO AND POLAR ELECTRO OY
AND
PHYSI-CAL ENTERPRISES,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI VOLUME II

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United States Patent [19]

Tehrani

[11] **Patent Number: 4,909,259**

[45] **Date of Patent: Mar. 20, 1990**

[54] **METHOD AND APPARATUS FOR DETERMINING METABOLIC RATE RATIO**

[76] Inventor: **Fleur T. Tehrani**, 2450 E. Nutwood, Apt. E 15, Fullerton, Calif. 92631

[21] Appl. No.: **341,413**

[22] Filed: **Apr. 21, 1989**

[51] **Int. Cl.**[4] **A61B 5/08**

[52] **U.S. Cl.** **128/718**; 128/670

[58] **Field of Search** 128/718, 719, 670, 671, 128/696, 713, 687

[56] **References Cited**

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3,802,698	4/1974	Burian et al.	272/57
3,870,034	3/1975	James	128/2.1
3,874,233	4/1975	Sanctuary et al.	73/194
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4,034,745	7/1977	Bloom	128/2.06
4,038,976	8/1977	Hardy et al.	128/285
4,058,118	11/1977	Stupay et al.	128/2.06
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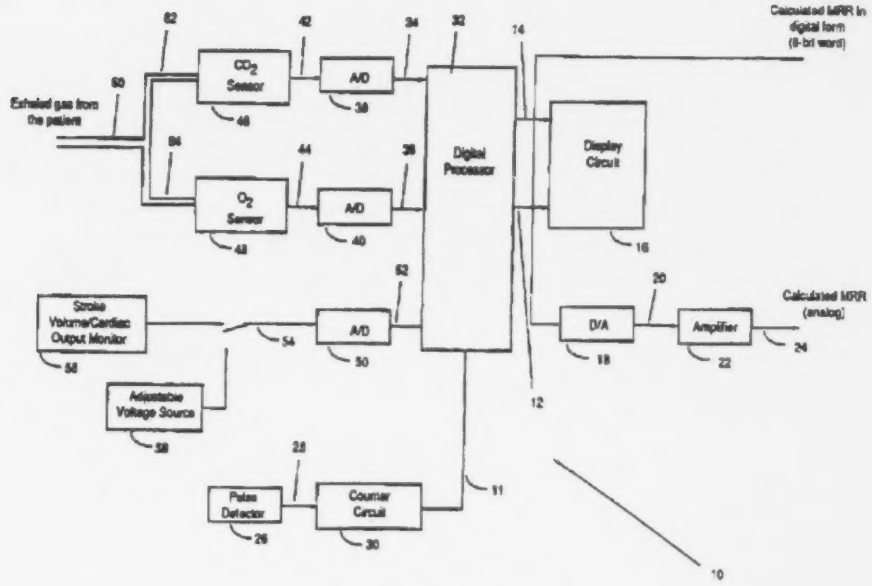
W. Fincham and F. T. Tehrani, "On The Regulation of Cardiac Output and Cerebral Blood Flow", *J. Biomed. Eng.*, vol. 5, pp. 73–75, Jan., 1983.

Primary Examiner—Lee S. Cohen
Assistant Examiner—Scott Getzow
Attorney, Agent, or Firm—Woodcock Washburn Kurtz Mackiewicz & Norris

[57] **ABSTRACT**

An apparatus and method determines the metabolic rate ratio (MRR) of a patient from data indicative of (a) oxygen and carbon dioxide concentrations of the patient, and (b) a cardiac function of the patient. The cardiac function data may be either heart rate and stroke volume of the patient, or cardiac output data from a cardiac output monitor than noninvasively and continuously monitors cardiac output. A CO_2 analyzer and either an O_2 analyzer or a pulse oximeter may be employed to provide the oxygen and carbon dioxide concentration data. Heart rate data is provided by either a pulse monitor or is obtained from the patient's ECG. The present invention permits measurement of MRR at any level of patient activity as well as during transitions in activity.

31 Claims, 10 Drawing Sheets



U.S. Patent Mar. 20, 1990 Sheet 1 of 10 4,909,259

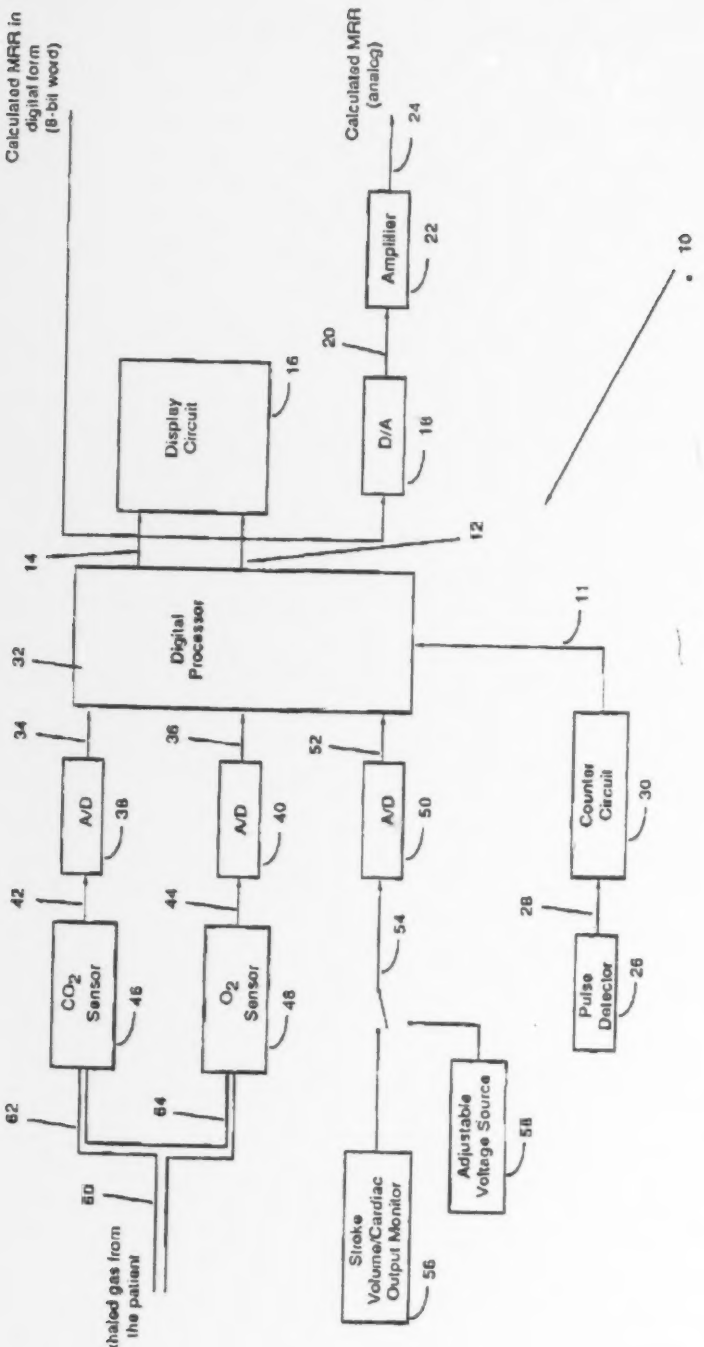


Fig. 1

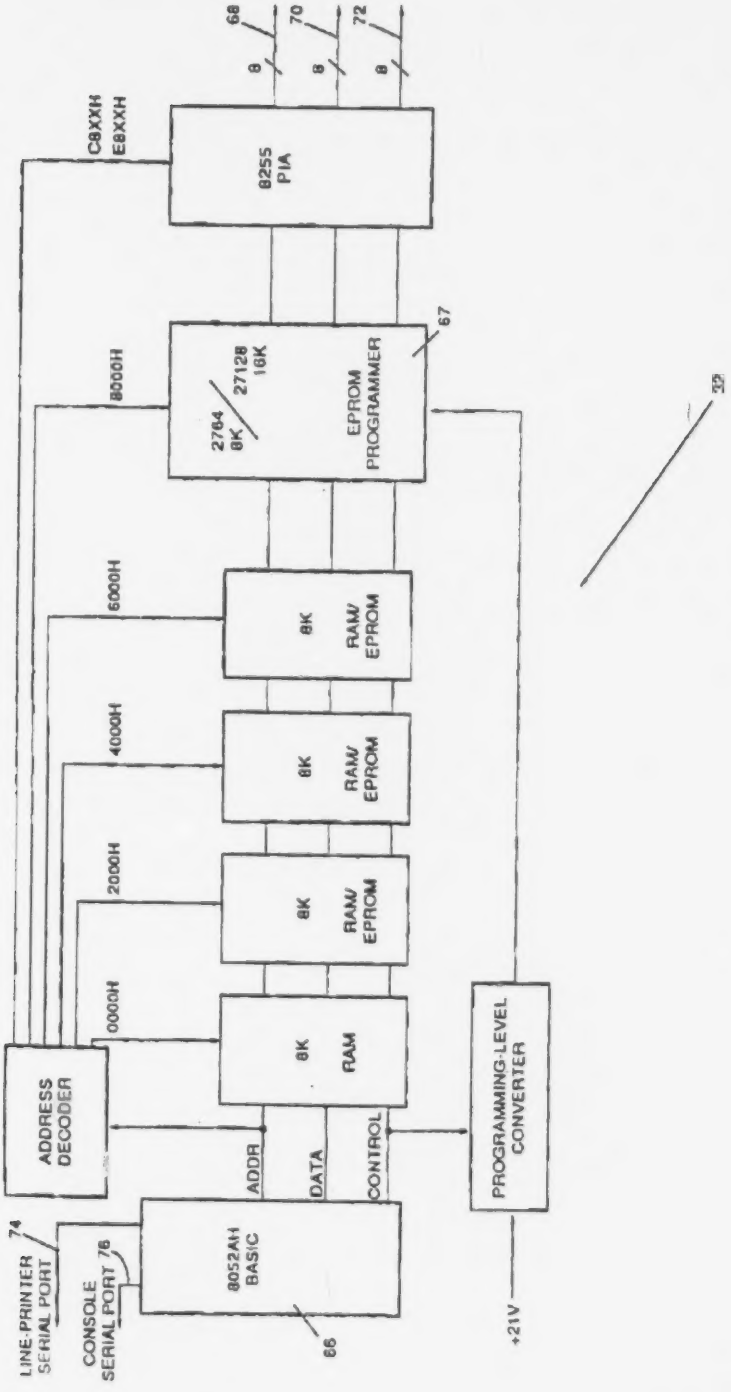

68
70
72
8
8
8
C8XXH
E8XXH
8255 PIA
8000H
2764 8K
27128 16K
EPROM PROGRAMMER
67
69
6000H
4000H
2000H
0000H
8K RAM/ EPROM
8K RAM/ EPROM
8K RAM/ EPROM
8K RAM
ADDRESS DECODER
ADDR
DATA
CONTROL
PROGRAMMING-LEVEL CONVERTER
+21V
74
LINE PRINTER SERIAL PORT
76
CONSOLE SERIAL PORT
8052AH BASIC
66

Fig. 2

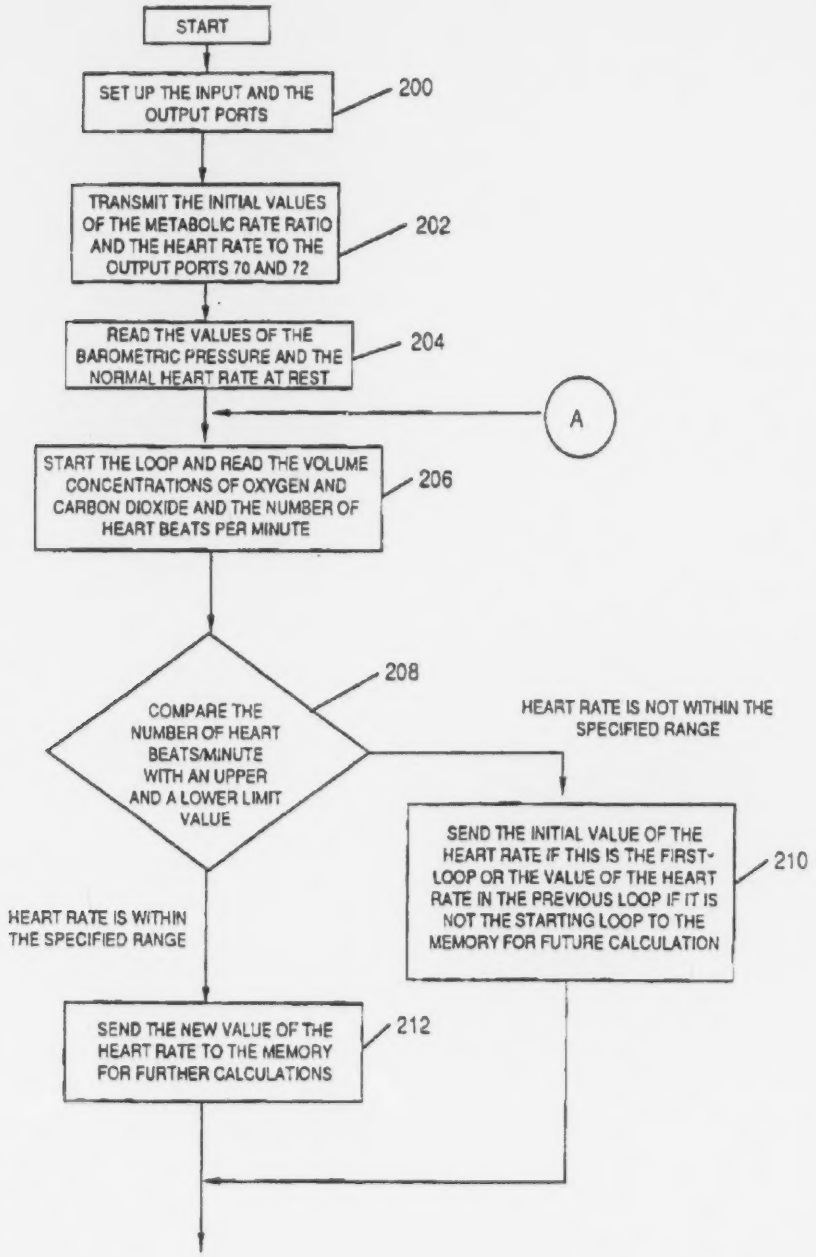

START
SET UP THE INPUT AND THE OUTPUT PORTS
200
TRANSMIT THE INITIAL VALUES OF THE METABOLIC RATE RATIO AND THE HEART RATE TO THE OUTPUT PORTS 70 AND 72
202
READ THE VALUES OF THE BAROMETRIC PRESSURE AND THE NORMAL HEART RATE AT REST
204
A
START THE LOOP AND READ THE VOLUME CONCENTRATIONS OF OXYGEN AND CARBON DIOXIDE AND THE NUMBER OF HEART BEATS PER MINUTE
206
COMPARE THE NUMBER OF HEART BEATS/MINUTE WITH AN UPPER AND A LOWER LIMIT VALUE
208
HEART RATE IS NOT WITHIN THE SPECIFIED RANGE
SEND THE INITIAL VALUE OF THE HEART RATE IF THIS IS THE FIRST LOOP OR THE VALUE OF THE HEART RATE IN THE PREVIOUS LOOP IF IT IS NOT THE STARTING LOOP TO THE MEMORY FOR FUTURE CALCULATION
210
HEART RATE IS WITHIN THE SPECIFIED RANGE
SEND THE NEW VALUE OF THE HEART RATE TO THE MEMORY FOR FURTHER CALCULATIONS
212

Fig. 3-A

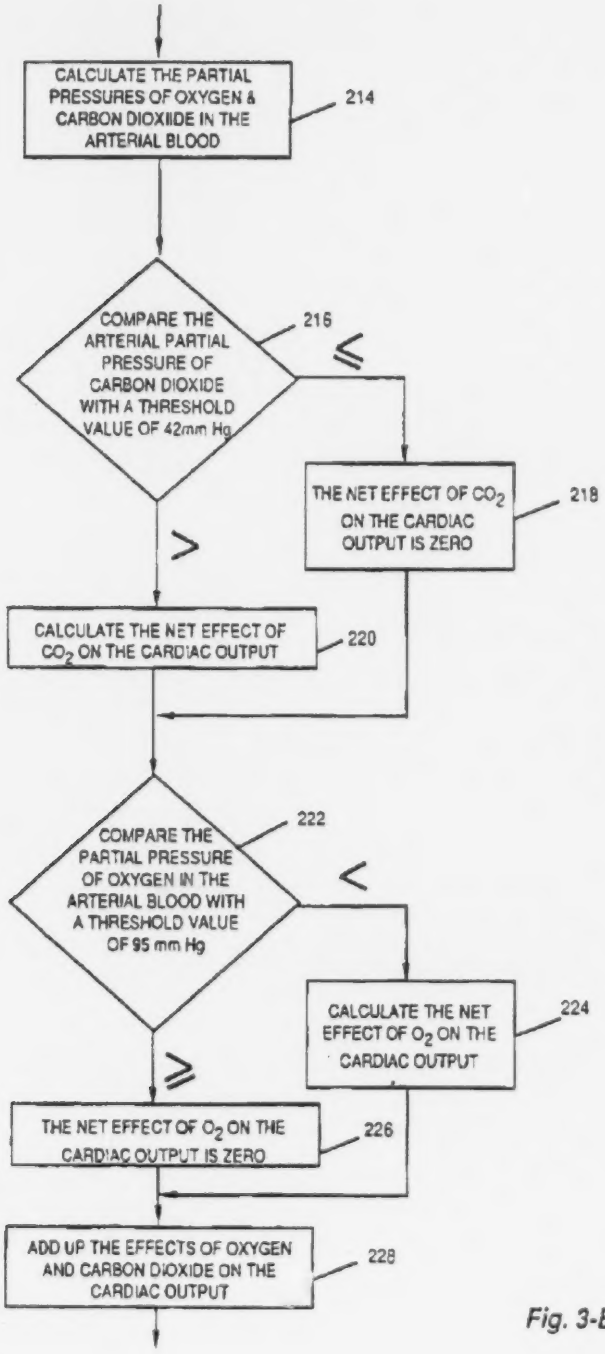

CALCULATE THE PARTIAL PRESSURES OF OXYGEN & CARBON DIOXIDE IN THE ARTERIAL BLOOD
214
COMPARE THE ARTERIAL PARTIAL PRESSURE OF CARBON DIOXIDE WITH A THRESHOLD VALUE OF 42mm Hg
216
≤
THE NET EFFECT OF CO_2 ON THE CARDIAC OUTPUT IS ZERO
218
>
CALCULATE THE NET EFFECT OF CO_2 ON THE CARDIAC OUTPUT
220
COMPARE THE PARTIAL PRESSURE OF OXYGEN IN THE ARTERIAL BLOOD WITH A THRESHOLD VALUE OF 95 mm Hg
222
<
CALCULATE THE NET EFFECT OF O_2 ON THE CARDIAC OUTPUT
224
≥
THE NET EFFECT OF O_2 ON THE CARDIAC OUTPUT IS ZERO
226
ADD UP THE EFFECTS OF OXYGEN AND CARBON DIOXIDE ON THE CARDIAC OUTPUT
228

Fig. 3-B

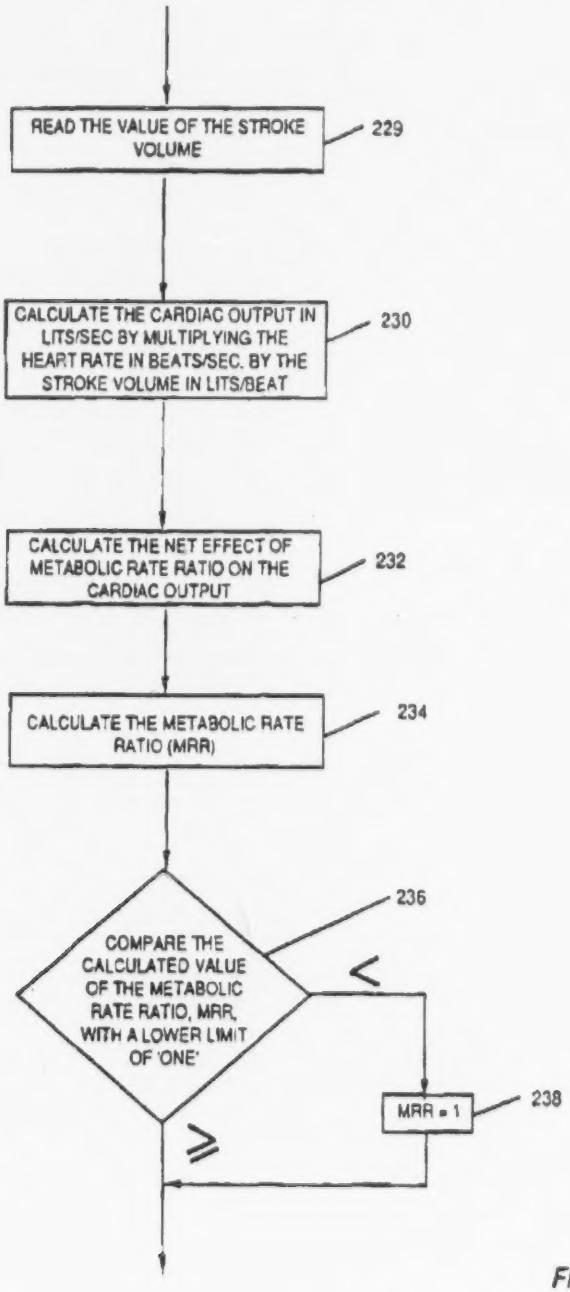

READ THE VALUE OF THE STROKE VOLUME
229
CALCULATE THE CARDIAC OUTPUT IN LITS/SEC BY MULTIPLYING THE HEART RATE IN BEATS/SEC. BY THE STROKE VOLUME IN LITS/BEAT
230
CALCULATE THE NET EFFECT OF METABOLIC RATE RATIO ON THE CARDIAC OUTPUT
232
CALCULATE THE METABOLIC RATE RATIO (MRR)
234
COMPARE THE CALCULATED VALUE OF THE METABOLIC RATE RATIO, MRR, WITH A LOWER LIMIT OF 'ONE'
236
<
≥
MRR = 1
238

Fig. 3-C

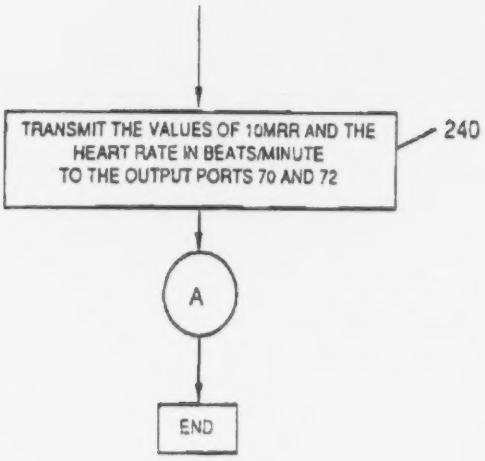

TRANSMIT THE VALUES OF 10MRR AND THE HEART RATE IN BEATS/MINUTE TO THE OUTPUT PORTS 70 AND 72
240
A
END

Fig. 3-D

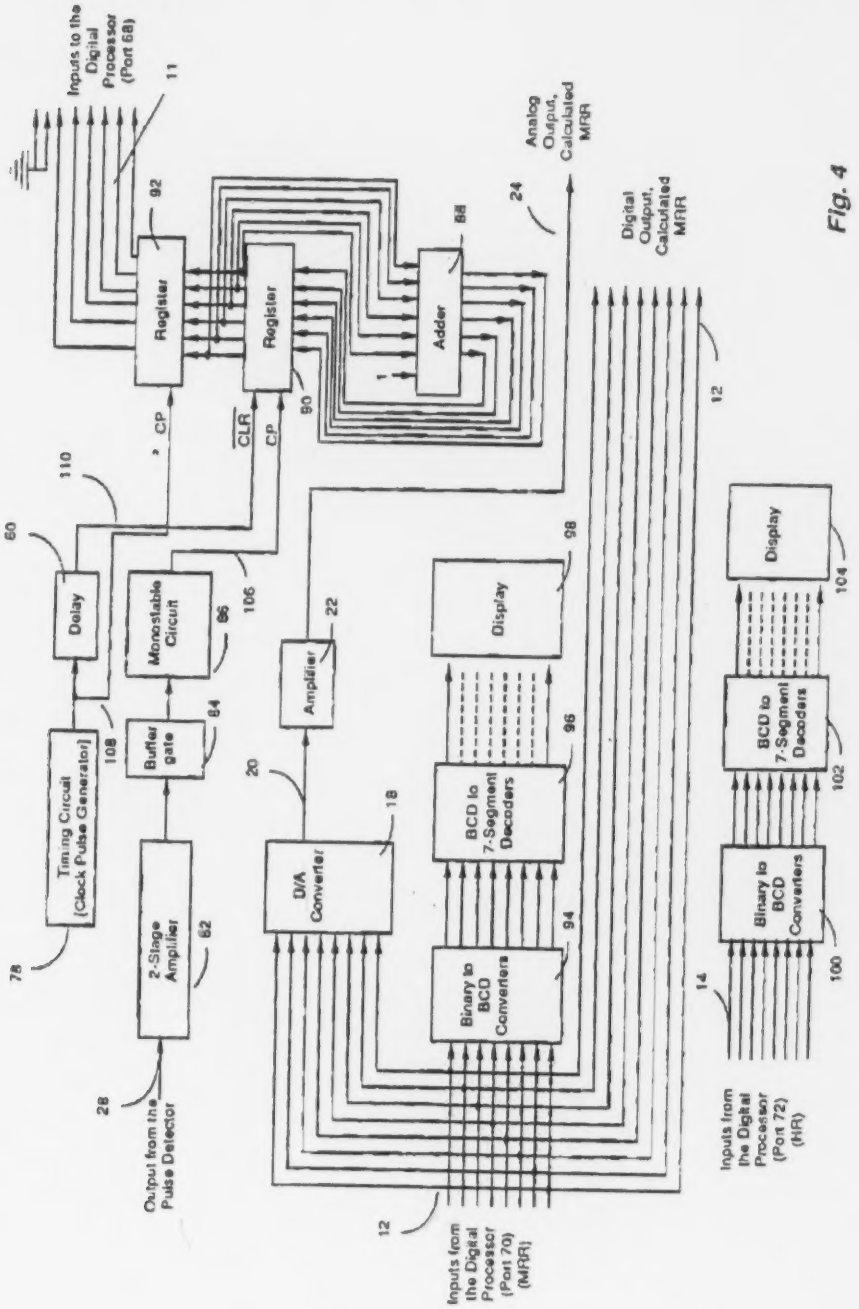

Inputs to the Digital Processor (Port 68)
11
92
Register
Register
Adder
84
24
Analog Output, Calculated MFR
Digital Output, Calculated MFR
90
12
CP
CLR
CP
110
60
Delay
Monostable Circuit
86
106
Amplifier
22
Display
98
Display
104
108
Timing Circuit (Clock Pulse Generator)
Buffer gate
84
20
BCD to 7-Segment Decoders
96
BCD to 7-Segment Decoders
102
78
2-Stage Amplifier
62
D/A Converter
18
Binary to BCD Converters
94
Binary to BCD Converters
100
14
28
Output from the Pulse Detector
12
Inputs from the Digital Processor (Port 70) (MFR)
Inputs from the Digital Processor (Port 72) (HR)

Fig. 4

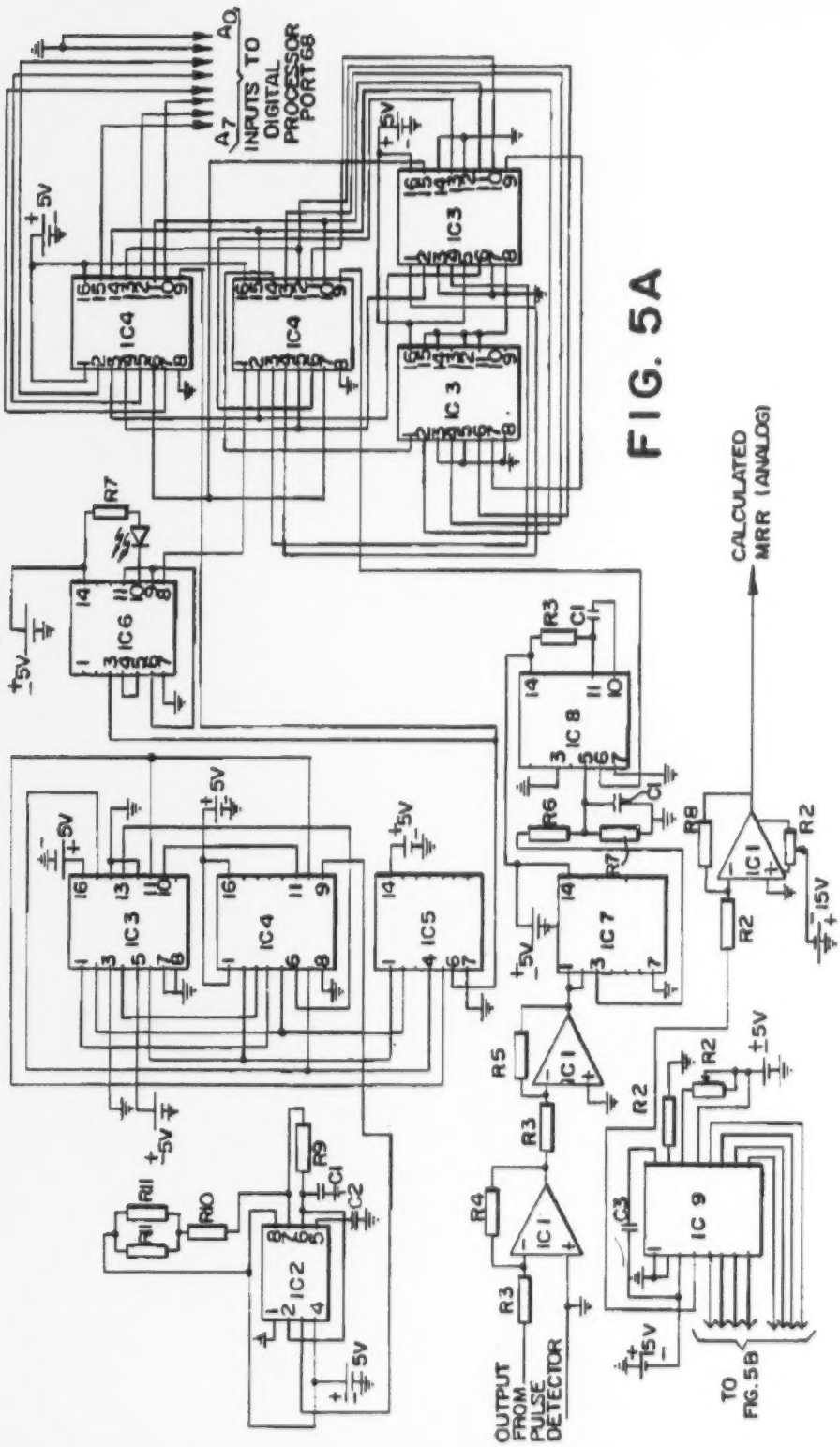
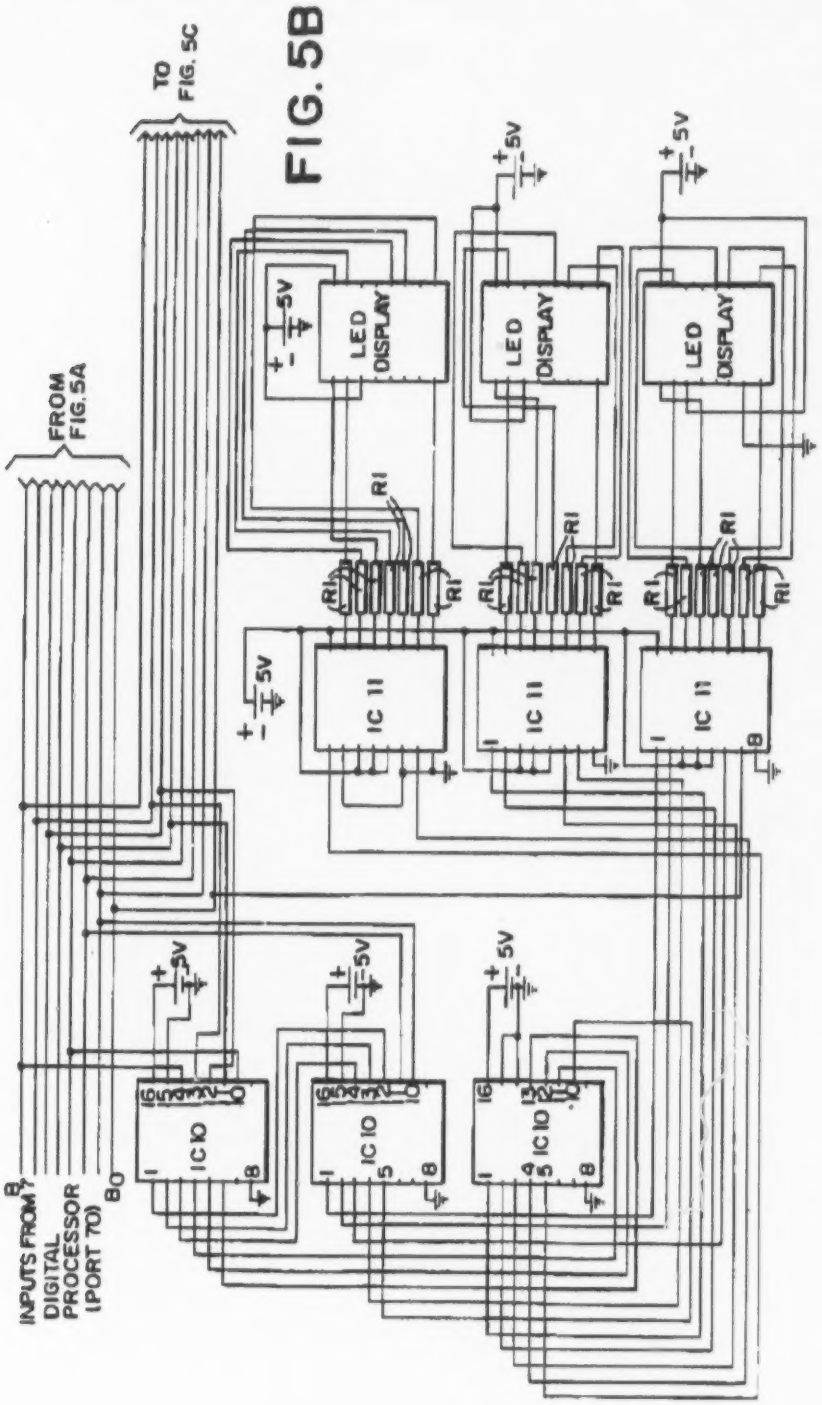

A0
A7
INPUTS TO DIGITAL PROCESSOR PORT 68
+5V
IC3
IC4
IC 3
IC4
IC 3
R7
IC6
+5V
R3
C1
IC 8
R6
C1
R7
IC 7
+5V
CALCULATED MRR (ANALOG)
R8
R2
IC1
R2
-15V
+5V
IC3
IC4
IC5
+5V
+5V
+5V
R5
IC1
R3
R2
R2
+5V
R4
IC1
R3
C3
IC 9
R9
C1
C2
R11
R10
IC2
+5V
+15V
-15V
OUTPUT FROM PULSE DETECTOR
TO FIG. 5B

FIG. 5A

FIG. 5B


TO FIG. 5C
FROM FIG. 5A
LED DISPLAY
LED DISPLAY
LED DISPLAY
+5V
+5V
+5V
R1
IC 11
IC 11
IC 11
IC 10
IC 10
IC 10
INPUTS FROM DIGITAL PROCESSOR (PORT 70)
B7
B0

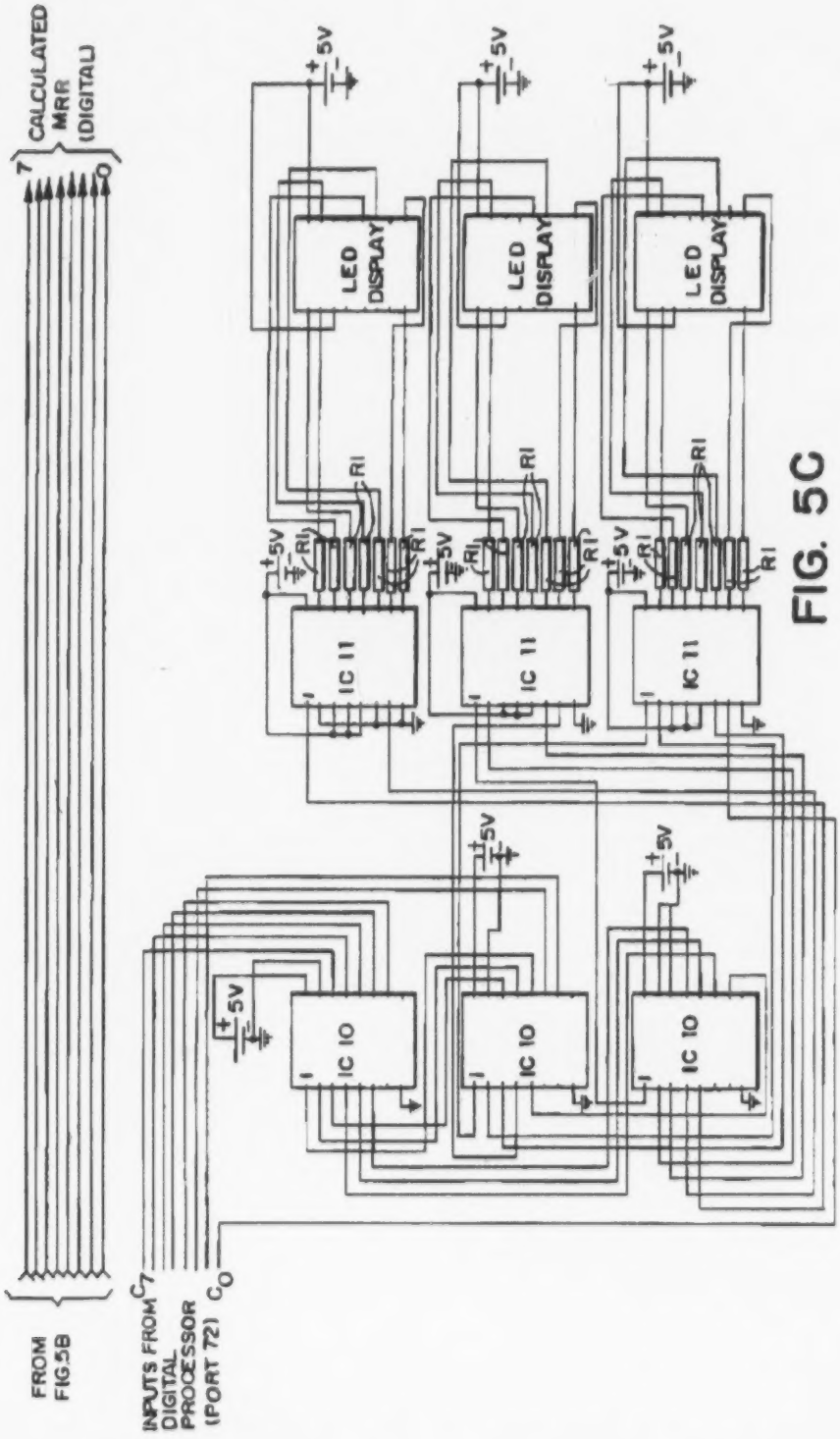

CALCULATED MRR (DIGITAL)
7
0
FROM FIG.5B
INPUTS FROM DIGITAL PROCESSOR (PORT 72)
C7
C0
+5V
LED DISPLAY
RI
IC 11
IC 10

FIG. 5C

METHOD AND APPARATUS FOR DETERMINING METABOLIC RATE RATIO

FIELD OF THE INVENTION

The present invention relates to a method and apparatus for determining a patient's metabolic rate ratio. More particularly, the present invention relates to a method and apparatus for determining a patient's metabolic rate ratio from (1) data indicative of carbon dioxide and oxygen pressures of the patient's arterial blood and (2) data indicative of either (a) the patient's heart rate and stroke volume, or (b) the patient's cardiac output if monitored noninvasively and continuously.

BACKGROUND OF THE INVENTION

Devices for determining the metabolic rate of a patient are generally known in the art. Known devices measure the patient's oxygen uptake by one means or another to provide a measure of metabolic rate. For example, U.S. Pat. No. 4,572,208, discloses a method and apparatus that measures oxygen uptake as an indicator of metabolic rate. Oxygen uptake can be measured: on a breath-by-breath basis, as taught by U.S. Pat. No. 4,368,740; by introducing a known amount of an inert gas (i.e., helium) into the patient's airways, as taught by U.S. Pat. No. 4,221,224; or by using an airtight system for patients under artificial respiration, as taught by U.S. Pat. No. 4,753,245.

These and other techniques require a system (either closed or open) for measuring the patient's oxygen consumption. In a closed system, a container of gas is required through which the patient inhales and exhales. Closed systems are acceptable for measurements taken under steady state conditions only. In an open system, the patient's amount of inhaled and exhaled gas are carefully monitored. In some systems, oxygen uptake is measured on a breath-by-breath basis. These systems require sophisticated sensors and gas flow meters to provide continuous output data during short transition periods.

In addition to the drawbacks noted above, a problem with using oxygen uptake as an indicator of metabolic rate is that the oxygen uptake of the human body reflects the rate of metabolism under steady state conditions only. Therefore, during transition periods in exercise and recovery, the patient's oxygen uptake cannot be used as a reliable indicator of metabolic rate.

The present invention is based upon the inventor's finding that a patient's metabolic rate ratio (MRR) can be reliably determined under both steady state and transient conditions without measuring oxygen uptake by employing data indicative of the patient's carbon dioxide and oxygen pressures of arterial blood and the patient's cardiac output. MRR is the ratio of the metabolic rate to basal rate of metabolism. In the practice of the invention, cardiac output data may be obtained by measuring heart rate and stroke volume. Various techniques have been described in the prior art for measuring heart rate. U.S. Pat. Nos. 4,034,745, 4,181,134, and 4,239,048 are representative. However, the prior art does not employ heart rate data to determine MRR, nor does the prior art provide data indicative of heart rate as well as MRR at different levels of activity.

It is, therefore, desirable to provide a method and apparatus for determining a patient's MRR at all levels of activity without complex or cumbersome equipment and without invasive physiological measurements.

SUMMARY OF THE INVENTION

The present invention relates to a method and apparatus for determining a patient's MRR using data indicative of CO_2 (carbon dioxide) and O_2 (oxygen) pressures of the patient's arterial blood and of the patient's cardiac output. The invention is based upon the findings that cardiac output increases rapidly and enormously as the MRR increases, and cardiac output increases as arterial CO_2 pressure increases and as arterial O_2 pressure decreases.

According to the invention, data indicative of the patient's arterial blood CO_2 pressure may be provided by a CO_2 analyzer. Data indicative of the patient's arterial blood O_2 pressure may be provided by either an O_2 analyzer or by a pulse oximeter that monitors the hemoglobin oxygen saturation of arterial blood. Cardiac output data may be obtained by at least one of two methods.

In a first method, data indicative of the patient's heart rate and stroke volume is provided, and the patient's cardiac output is computed therefrom. Heart rate is measured on a continuous basis, either from the output of a pulse monitor that provides a systolic pulse signal or from an ECG (electrocardiogram) signal. The invention is not limited to these means of measuring heart rate. Stroke volume is measured either on a continuous basis or is measured once, prior to operation of the system described herein, and provided as a constant. Known means for measuring stroke volume are disclosed herein.

In a second method, data indicative of the patient's cardiac output is directly provided by a cardiac output monitor provided that such device noninvasively and continuously monitors cardiac output.

A method for measuring a patient's MRR according to the present invention comprises the steps of:

(a) providing data indicative of oxygen and carbon dioxide concentrations of the patient;

(b) determining, based upon the data indicative of the patient's oxygen and carbon dioxide concentrations and data indicative of barometric pressure, the partial pressures of oxygen and carbon dioxide in arterial blood of the patient;

(c) determining, based upon the results of step (b), net effects of oxygen and carbon dioxide in the arterial blood on cardiac output of the patient;

(d) determining, based upon data indicative of cardiac output of the patient and the result of step (c), net effect of metabolic rate ratio on blood flow of the patient; and,

(e) determining, based upon the result of step (d), the metabolic rate ratio of the patient and providing output data indicative thereof.

Knowing the basal rate of metabolism, the metabolic rate can be easily obtained from the output data indicative of the metabolic rate ratio.

The data indicative of the oxygen and carbon dioxide concentrations and the data indicative of the patient's cardiac output may be obtained as described above.

Apparatus for carrying out the method of the invention may comprise:

(a) first means for providing data indicative of oxygen and carbon dioxide concentrations of the patient;

(b) second means for providing data indicative of a cardiac function of the patient;

(c) third means for processing the data provided by the first and second means and providing output indicative of the MRR of the patient by:

(i) determining, based upon the data indicative of the patient's oxygen and carbon dioxide concentrations, and data indicative of barometric pressure, the partial pressures of oxygen and carbon dioxide in arterial blood of the patient;

(ii) determining, based upon the results of step (i), net effects of oxygen and carbon dioxide in the arterial blood on cardiac output of the patient;

(iii) determining, based upon data indicative of cardiac output of the patient and the result of step (ii), net effect of metabolic rate ratio on blood flow of the patient; and,

(iv) determining, based upon the result of step (iii), the metabolic rate ratio of the patient.

According to the invention, a suitably programmed microprocessor comprises the third means and performs each of the functions thereof according to an algorithm disclosed herein. Analog to digital converters are employed to convert analog data from the CO_2 and O_2 analyzers (and/or pulse oximeter) and, if desired to be monitored continuously, stroke volume monitor to digital data for processing by the microprocessor. Heart rate data may be provided by direct digital input to the microprocessor (e.g., from a counter circuit receiving clock pulses from a pulse detector). A digital display circuit may provide a visual display of MRR and heart rate data. A digital-to-analog converter and appropriate amplification may be provided to drive additional circuitry, for example, a chart recorder, as desired.

It is an object of the present invention to provide an apparatus and method for reliably measuring a patient's metabolic rate ratio during periods of activity, rest and transition therebetween of a patient.

It is a further object of the present invention to provide a system for determining a patient's metabolic rate ratio using data indicative of CO_2 and O_2 pressures of the patient's arterial blood and cardiac output, the latter either being computed from heart rate and stroke volume data provided to the system or being provided by a cardiac output monitor, if of a type that noninvasively and continuously monitors cardiac output. In the inventor's presently pending patent application, Ser. No. 233,455, mention is made of using a metabolic rate ratio monitor to provide additional data to the controller of an artificial respirator. The apparatus and method described herein may be used to provide the required data to the system disclosed in that application. The output data provided by the apparatus of the present invention can also be used in exercise monitoring systems and many other similar applications.

These and other novel objects, advantages and features of the present invention will become more apparent from the following detailed description and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of an MRR measuring system embodying the present invention.

FIG. 2 is a block diagram of a programmable processor employed in a preferred embodiment of the present invention.

FIGS. 3A-3D are a flow chart illustrating a method for determining MRR according to a preferred embodiment of the present invention.

FIG. 4 is a detailed block diagram of a preferred embodiment of circuitry for practicing the present invention.

FIGS. 5A, 5B and 5C are a circuit diagram illustrating a preferred embodiment of the block diagram of FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is described herein in four sections as follows: introduction to apparatus of the invention; apparatus according to the invention; introduction to method of the invention; and, method according to the invention.

Introduction to Apparatus

The present invention employs data indicative of the CO_2 and O_2 pressures of a patient's arterial blood and of the patient's cardiac output to calculate the patient's metabolic rate ratio. Cardiac output data may be obtained by at least one of two methods.

In a first method, data indicative of the patient's heart rate and stroke volume is provided and the patient's cardiac output is computed therefrom. Heart rate data is obtained from a systolic pulse signal provided by a pulse monitor or is derived from an ECG (electrocardiogram) signal. The invention is not limited to these means of measuring heart rate. Stroke volume is provided by a noninvasive monitor of any suitable type such as described in the following U.S. patent literature and incorporated herein by reference: U.S. Pat. Nos. 4,450,527; 4,137,910; and, 4,509,526. The patient's stroke volume may be measured when the patient is in a desired posture, for example, standing, sitting or supine, using any of the techniques disclosed in the above patents, or many other techniques known to those skilled in the art, prior to operation and provided to the system as a constant.

In a second method, data indicative of the patient's cardiac output is directly provided by a cardiac output monitor provided that such device noninvasively and continuously monitors cardiac output. Such apparatus have been described in the patent literature. See, e.g., U.S. Pat. Nos. 4,437,469 and 4,676,253, incorporated herein by reference.

CO_2 and O_2 analyzers coupled to receive exhaled gas from a patient may be employed to provide the data indicative of the arterial pressures of CO_2 and O_2. Alternatively, in the case of O_2, a pulse oximeter may be employed to provide the same data by monitoring the hemoglobin O_2 saturation of arterial blood.

According to the disclosed embodiment, the apparatus includes a microprocessor for processing this data and determining therefrom the patient's MRR according to the method described herein.

Apparatus

Referring now to the drawings wherein the like reference numbers represent like elements, there is illustrated in FIG. 1, in summary detail, a preferred embodiment of a measuring/monitoring system provided in accordance with this invention and designated generally as 10. As shown, exhaled gas from a patient is passed through an expiration line 60. Expiration line 60 is coupled at one end to CO_2 and O_2 sensors 46, 48 via inlets 62, 64. The other end is coupled to an endotracheal tube or a mouthpiece (not shown) which is used to collect the patient's exhaled gas. The exhaled gases

from the patient are analyzed by the CO_2 and O_2 sensors 46, 48 to provide data indicative of the patient's concentrations of CO_2 and O_2, respectively. (If system 10 is employed as an exercise monitoring system for a normal healthy subject, analysis of the exhaled gases will not be necessary since the arterial pressures of O_2 and CO_2 for the subject in light to moderate exercise do not differ significantly from their normal values at rest.)

In an alternative embodiment, the O_2 sensor 48 may be substituted with a pulse oximeter in which case the exhaled gases will pass to CO_2 sensor 46 only. The output of a pulse oximeter represents the hemoglobin O_2 saturation of the arterial blood and can be converted to the arterial pressure of O_2. Reference will hereafter be made to O_2 analyzer 48, but it should be understood that, except as indicated, this is not intended to exclude substitution of a pulse oximeter, and therefore, all such references include a pulse oximeter.

Analog signals 42 and 44 from the two sensors 46, 48 are converted to digital data by two A/D converters 38 and 40. This digital data is provided to a processor 32 as shown at 34, 36. The processor may be a Micromint brand BCC52 Basic controller board, however, any suitable processor may be employed. The A/Ds 38, 40 may comprise a portion of a multiple channel A/D board that samples the input signals and converts them to digital outputs at a fixed rate, e.g., every 640 microseconds. Outputs 34 and 36 may be two output channels of the A/D board.

The patient's stroke volume may comprise another input to processor 32. If provided, the stroke volume can either be continuously monitored using an appropriate noninvasive measuring technique or measured prior to operation of the system at any desired posture and applied as a constant input to the system. The latter is possible since stroke volume is affected mainly by the subject's posture and, after a slight increase during the transition from rest to exercise, remains fairly constant at different levels of activity. Stroke volume may be measured by a monitor 56 of a type described above and an analog output 54 therefrom, representing the patient's stroke volume, may be applied to the input of an A/D converter 50. Alternatively, if it is not desired to monitor stroke volume continuously, a representative value (e.g., obtained from the patient prior to operation of the system) may be stored in software of the processor 32 or supplied to the input of A/D converter 50 from a fixed adjustable voltage source 58. The digital output of the A/D 52 is supplied to the digital processor 32 as shown.

A pulse detector 26 may provide a systolic pulse signal 28 to counter circuit 30. A pulse detector with a photoelectric cell transducer may be used to detect systolic pulses of the subject, for example, at the finger. Alternatively, the patient's ECG signal can be provided as the input to counter 30. The counter 30, whose output represents the patient's heart rate, counts the number of signals occurring over a selected period of time, e.g., every 15 seconds, and provides this count to processor 32 as shown at 11.

The processor 32 is shown as providing two digital outputs. One of the outputs 12 provides the calculated digital value of the patient's MRR. The other output 14 provides the patient's heart rate in beats per minute. The first output 12 is coupled to a D/A converter 18. The output 20 of D/A converter 18 is applied to an amplifier circuit 22. The output of the amplifier 24 is an analog signal indication of the patient's metabolic rate ratio and may be used to drive additional circuitry such as a chart recorder. In preferred embodiments, output 24 varies from 0.6 to 4.2 volts for MRRs between 1 and 7. As shown, the processor's outputs 12 and 14 are applied to a display circuit 16 for providing a visual display of the output data.

In the schematic diagram of FIG. 2, a block diagram of processor 32 is illustrated. Processor 32 may employ an Intel 8052AH-BASIC, 8-bit microcontroller chip 66 which contains 8k bytes ROM on the chip as a BASIC interpreter and 256 bytes of RAM. The processor 32 has 48K bytes of RAM/EPROM, a 2764/128 EPROM programmer, three parallel I/O ports designated as 68, 70 and 72, a serial line printer port 74, and a serial terminal port 76. 8052AH-BASIC chip 66 has a 16-bit address and an 8-bit data bus. The eight least significant address bits and the data bus are multiplexed together. Preferably, the control program is saved on an EPROM and is executed continuously after resetting the processor at the beginning of operation.

Referring to FIG. 4, counter circuit 30, display circuit 16, D/A converter 18 and amplifier 22 are illustrated in greater detail. The output from pulse detector 28 is applied to a 2-stage amplifier 82. The 2-stage amplifier is designed so that the current drawn from the pulse detector circuit is limited. The output of this amplifier is applied to a buffer gate 84 which provides either zero or five volts corresponding respectively to low and high levels of the input voltage. The sequence of pulses at the output of the buffer gate 84 is applied to a monostable circuit 86 which acts as a clock pulse generator for register circuit 90. Monostable circuit 86 acts as a pulse shaper and generates a train of sharp and clean pulses 106 for register circuit 90.

Timing circuit 78 generates a clock pulse at a specific frequency. In preferred embodiments, the period of this clock pulse is 15 seconds, but can be reduced if necessary. The output of timing circuit 78, designated at 108, is a clock pulse for register circuit 92. Output 108 is delayed by about 70 nanoseconds by delay circuit 80, and the output of the delay circuit, designated as 110, is applied to the clear line of register 90. The 6-bit output of register 90 is the input to 6-bit adder 88. The least significant bit of one of the inputs to the adder circuit 88 is permanently connected to logic "1", and the other bits are at logic "0", i.e., grounded.

The other 6-bit input is connected to the outputs of register 90. The outputs of adder 88 provide the 6-bit input to register 90. The outputs of register 90 are also connected to the inputs of register 92. When a pulse arrives on 110 at the clear line of register 90, the outputs of register 90 are cleared. Then, by arrival of every pulse at 106 (output 106 represents the heartbeat sequence), the 6-bit input of the parallel-in parallel-out register 90 appears at its output. This output is immediately incremented by "1" at the output of adder 88. The output of adder 88 is connected to the input of register 90.

Therefore, by arrival of every pulse at 106, the output of register 90 is incremented by "1" until another pulse appears at 108 after a specific period, e.g., 15 seconds. At this time, register 92 is clocked, and the output of register 90 is transferred to the output of register 92. After a delay of about 70 nanoseconds which is used to provide sufficient time for the transfer of the inputs to the outputs of register 92, the pulse generated at 108 appears at 110 and clears the register 90.

This procedure is repeated, e.g. every 15 seconds. Thus, the 6-bit output of register **92** is the number of heartbeats counted over a 15-second period. This 6-bit word is shifted 2 bits to the left, which is the same as being multiplied by a factor of **4**, and the resulting 8-bit word **11** is applied to port **68** of the main processor. Output **12** from port **70** of the main processor, which is an 8-bit word representing the calculated value of the metabolic rate ratio, is accessible at the output of the circuit. This value is also converted to analog using a D/A converter **18** and amplified by an amplifier circuit **22** and is accessible at the output of the circuit to represent the calculated value of the MRR in analog form **24**. In preferred embodiments, this analog voltage varies from 0.6 to 4.2 volts for MRRs changing between **1** and **7**.

The digital word **12** from port **70** of the main processor is also applied to a binary to BCD converter circuit **94**. The outputs of this circuit are used as the inputs to circuit **96** which are BCD to 7-segment decoders. The outputs from block **96** are applied to 7-segment LEDs, circuit **98**, which displays the value of the MRR. The other output of the main processor from port **72**, which is an 8-bit word representing the heart rate in beats per minute, is applied to another binary to BCD converter circuit **100**. The outputs of **100** are used as the inputs to circuit **102** which are BCD to 7-segment decoders. The outputs of **102** are applied to 7-segment LEDs, circuit **104**, to display the heart rate in beats per minute.

FIGS. **5A**, **5B** and **5C** are a detailed circuit diagram illustrating counter circuit **30**, D/A converter **18**, amplifier circuit **22** and display circuit **16**. The component types and their values are shown in the chart below.

NAME	COMPONENT ID OR VALUE	NAME	COMPONENT ID OR VALUE
R1	150 ohms	IC3	SN74LS283N
R2	1K ohms	IC4	SN74LS174ND
R3	10K ohms	IC5	N7421A
R4	100K ohms	IC6	SN7404N
R5	22K ohms	IC7	MC14071
R6	100K ohms	IC8	SN74121N
R7	390 ohms	IC9	AM14088N
R8	2.7K ohms	IC10	SN74185AN
R9	6.5 M ohms	IC11	SN7447AN
R10	1 M ohms		
R11	620K ohms		
C1	0.1 micro farad		
C2	0.01 micro farad		
C3	11 pico farad		
IC1	741CN		
IC2	CA555C6		

Introduction to Method

Carciac output can be considered as a function of the rate of metabolism and the CO_2 and O_2 pressures of arterial blood. The patient's blood flow can be modeled as:

$$\frac{dQ}{dT} = Q'_M + Q'_C \qquad \text{(equation 1)}$$

where dQ/dT is the cardiac output or the blood flow, Q'_C is a function of the arterial pressures of CO_2 and O_2, and Q'_M is a function of the metabolic rate. The relationship between the cardiac output and CO_2 pressures of arterial blood can be expressed as:

$$Q'(CO_2)=0.0045\ (paCO_2-42),\ \text{for } PaCO_2>42 \text{ mm Hg} \qquad \text{(equation 2)}$$

and:

$$Q'(CO_2)=0,\ \text{for } PaCO_2\leq 42 \text{ mm Hg.} \qquad \text{(equation 3)}$$

In equations 2 and 3, $Q'(CO_2)$ is the net effect of the arterial pressures of CO_2 on the cardiac output in liters/second and $PaCO_2$ represents the partial pressure of CO_2 in the arterial blood in millimeters of mercury (mm Hg).

The relationship between cardiac output and the arterial O_2pressure is provided using the following mathematical expressions:

$$Q'(O_2) = 244.509 \times 10^{-4} T_0(X) - 323.328 \times 10^{-4} T_1(X) + 105.044 \times 10^{-4} T_2(X) - 143.505 \times 10^{-5} T_3(X), \qquad \text{(equation 4)}$$

for $PaO_2 < 95$ mm Hg,

and:

$$Q'(O_2)=0,\ \text{for } PaO_2\geq 95 \text{ mm Hg} \qquad \text{(equation 5)}$$

where:

$$X = \frac{2PaO_2 - 115}{65}. \qquad \text{(equation 6)}$$

In the above expressions, $Q'(O_2)$ is the net effect of the arterial pressure of O_2 on the cardiac output in liters/seconds, PaO_2 is the arterial pressure of O_2 in mm Hg and $T_j(X)$ is the Chebyshev polynomial of the first kind with degree (j) and argument (X). Q'_C, which was defined earlier as the effect of CO_2 and O_2 pressures of arterial blood on the cardiac output, can be written as:

$$Q'_C = Q'(CO_2) + Q'(O_2). \qquad \text{(equation 7)}$$

Q'_M, defined as the net effect that the metabolic rate ratio has on the cardiac output, can be expressed as a function of the metabolic rate ratio in the following manner:

$$Q'_M = 158.5674 \times 10^{-2} T_0(Y) + 617.519 \times 10^{-4} T_1(Y) \qquad \text{(equation 8)}$$

where:

$$Y = \frac{2MRR - 7}{5}. \qquad \text{(equation 9)}$$

In equations 8 and 9, Q'_M is expressed in liters/ second, MRR represents the metabolic rate ratio and $T_j(Y)$ is the Chebyshev polynomial of the first kind of degree (j) with argument (Y). When determining the metabolic rate ratio, arterial pressures of CO_2 and O_2 are derived from the values of the input data provided by CO_2 and O_2 sensors and $Q'(CO)_2$) and $Q'(O_2)$ are calculated using equations 2, 3, 4, 5 and 6. The cardiac output can be determined from the heart rate and data indicative of the stroke volume. Then, using equations 7 and 1, Q'_C and Q'_M can be calculated. Alternatively, stroke volume may be measured prior to operation of the apparatus and provided as an input to the system instead of being continuously monitored, as described above. If a cardiac output monitor of the type hereinabove described is employed, then cardiac output can be taken directly

from the monitor, in which case there is no need to measure heart rate or stroke volume. The metabolic rate ratio can be calculated from Q'_m using equations 8 and 9. Knowing the basal rate of metabolism, the metabolic rate can be easily obtained from the output data indicative of the MRR.

The apparatus and method disclosed herein may be simplified if used for normal, healthy individuals. For a healthy subject, the arterial pressures of CO_2 and O_2 in light-to-moderate exercise remain within a normal range at rest. Under these conditions, $Q'(CO_2)$ and $Q'(O_2)$ from equations 3 and 5 will be zero, and there is no need to use CO_2 and O_2 sensors in the system.

METHOD

Referring to FIGS. 3A–3D, a flow chart of a computer program embodying the method of the present invention is illustrated.

As can be seen at the beginning of the flow chart, the input and output ports of processor **32** are set up at **200**. At the next step **202**, initial values of the MRR and the heart rate at rest are transmitted to the output ports **70** and **72** of the processor **32**. In step **204**, values of the barometric pressure and the heart rate at rest are entered into the processor **32**. These values may be supplied via two reserved channels of the A/D board or may be stored in software. At the next step **206**, a program loop is started at "A" and the volume concentrations of CO_2 and O_2 in exhaled gases are entered through the A/D converters **38**, **40**. Also at this step, the number of heart beats per minute or the number of heart beats counted over any other specified time period from the counter circuit **30**, is entered through the port **68**. As mentioned, the value of arterial hemoglobin O_2 saturation may be supplied to the processor by using a pulse oximeter instead of an O_2 gas sensor.

In step **208**, the number of heart beats per minute is compared with a lower and upper limit value. The limit values are typically **50** and **220** beats per minute, respectively. If the heart rate is found to be outside the specified range, step **210** is executed in which the supplied value for the heart rate is disregarded and the heart rate value used in the previous loop is maintained in the memory for future calculations. If it happens to be the first loop of program execution, the initial value of the heart rate at rest, read at the beginning of the program at step **204**, is stored in memory for further calculations. If as a result of the comparison at step **208** the heart rate is found to be within the specified range, its value is accepted at step **212** and stored in memory for further computations.

At step **214**, the partial pressures of O_2 and CO_2 in the patient's arterial blood are calculated using the following equations:

$$PaCO_2 = C_{CO_2}(P_B - 47) - K_1 \qquad \text{(equation 10)}$$

$$PaO_2 = C_{O_2}(P_B - 47) - K_2, \qquad \text{(equation 11)}$$

where $PaCO_2$ and PaO_2 are the partial pressures of CO_2 and O_2 in the arterial blood in mm Hg, C_{CO_2} and C_{O_2} are the volume concentrations of CO_2 and O_2 in the exhaled gases, K_1 and K_2 are two constants representing the average differences between the alveolar and arterial pressures of CO_2 and O_2 in mm Hg, P_B is the barometric pressure in mm Hg, and **47** is the partial pressure of water vapor in the alveoli space in mm Hg. If a pulse oximeter is used for monitoring the blood O_2 level instead of an O_2 gas sensor, the following equation is used at this step to determine the partial pressure of O_2 in the arterial blood:

$$PaO_2 = \frac{-\ln[1 - (SaO_2)^4]}{0.046}, \qquad \text{(equation 12)}$$

where PaO_2 represents the partial pressure of O_2 in the arterial blood in mmHg and SaO_2 is the arterial hemoglobin O_2 saturation monitored by the oximeter.

In the next step **216**, the partial pressure of CO_2 in the arterial blood is compared with a threshold value of 42 mm Hg. If the partial pressure of CO_2 is less than or equal to the threshold value, step **218** is executed in which the net effect of CO_2 on the cardiac output is set to zero. However, if the partial pressure of CO_2 in the patient's arterial blood is greater than the threshold value, the net effect of CO_2 on the cardiac output is calculated using equation 2 at step **220**.

At step **222**, the partial pressure of O_2 in the arterial blood, PaO_2 is compared with a threshold value of 95 mm Hg. If the partial pressure of O_2 is found to be less than the threshold value, step **224** is executed in which the net effect of the blood O_2 level on the cardiac output is calculated using equations 4 and 6. If as a result of the comparison at step **222** PaO_2 is found to be greater than or equal to the threshold value, step **226** is executed in which the net effect of O_2 on the cardiac output is set to zero. At step **228** that follows, the net effects of the CO_2 and O_2 levels in the patient's arterial blood on the cardiac output are summed up using equation 7.

In the next step **229**, the value of the patient's stroke volume is entered. This value is either monitored continuously or is measured prior to operation of the system at a desired posture and supplied to the processor as a constant. The stroke volume may be read from one of the input channels or stored in software if it is not continuously monitored. In step **230**, cardiac output is calculated by multiplying the heart rate (in beats per second) by the stroke volume (in liters per beat). Using equation 1 at the next step **232**, the sum of the effects of CO_2 and O_2 levels in the patient's arterial blood on the cardiac output, found at **228** (Q'_c), is subtracted from the cardiac output calculated at 230 (dQ/dT), to determine the net effect of the metabolic rate ratio on the blood flow, Q'_M.

Having found the value of Q'_M, the metabolic rate ratio is calculated using equations 8 and 9 at step **234**. At step **236**, the calculated value of the metabolic rate ratio, MRR, is compared with a minimum value of 1. If the metabolic rate ratio is less than this value, it is increased to 1 at step **238** and then step **240** is executed. However, if the calculated ratio is greater than or equal to the minimum value, step **240** is executed after step **236**. At step **240** the values of 10 times MRR, and the heart rate in beats per minute, determined at either step **210** or **212**, are transmitted to the output ports **70** and **72**. After the execution of step **240**, the program control returns to "A" and another loop is started.

CONCLUSION

There has been described a preferred embodiment of an apparatus and method for determining a patient's metabolic rate ratio. The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. Accordingly, reference should be made to the appended claims,

rather than to the foregoing specification, as indicating the scope of the invention.

What is claimed is:

1. Apparatus comprising:

(a) first means for providing data indicative of a cardiac function of a patient; and,

(b) second means for determining the patient's metabolic rate ratio based upon the data provided by the first means.

2. Apparatus according to claim 1 further comprising third means for providing data indicative of oxygen and carbon dioxide concentrations of the patient, the second means determining the patient's metabolic rate ratio based upon the data provided by the first and third means.

3. Apparatus according to claim 2 wherein the third means comprises CO_2 and O_2 analyzers for analyzing exhaled gas of the patient.

4. Apparatus according to claim 2 wherein the third means comprises a CO_2 analyzer and a pulse oximeter.

5. Apparatus according to claim 2 wherein the second means comprises a processor programmed to determined the patient's metabolic rate ratio by:

(a) determining, based upon the data indicative of the patient's oxygen and carbon dioxide concentrations, and data indicative of barometric pressure, the partial pressures of oxygen and carbon dioxide in arterial blood of the patient;

(b) determining, based upon he results of step (a), net effects of oxygen and carbon dioxide in the arterial blood on cardiac output of the patient;

(c) determining, based upon data indicative of cardiac output of the patient and the result of step (b), net effect of metabolic rate ratio on cardiac output of the patient; and,

(d) determining, based upon the result of step (c), the metabolic rate ratio of the patient.

6. Apparatus according to claim 1 wherein the first means comprises a heart rate monitor.

7. Apparatus according to claim 6 wherein the heart rate monitor comprises a pulse monitor for providing a systolic pulse signal.

8. Apparatus according to claim 6 wherein the heart rate monitor comprises means for processing an ECG signal.

9. Apparatus according to claim 6 further comprising a stroke volume monitor.

10. Apparatus according to claim 1 wherein the first means comprises a cardiac output monitor.

11. Apparatus comprising:

(a) first means for analyzing gas exhaled by a patient and providing output dates indicative of volume concentration of at least one of CO_2 and O_2 in the gas;

(b) second means for providing data indicative of heart rate of the patient; and,

(c) third means receiving data from the first and second means for computing therefrom data indicative of the patient's metabolic rate ratio.

12. Apparatus according to claim 11 wherein the first means further comprises CO_2 and O_2 analyzers.

13. Apparatus according to claim 11 wherein the first means comprises a CO_2 analyzer and a pulse oximeter.

14. Apparatus according to claim 11 further comprising fourth means for providing data indicative of the patient's stroke volume, the third means determining the patient's cardiac output from the heart rate and stroke volume data.

15. Apparatus according to claim 14 wherein the fourth means continuously monitors the patient's stroke volume and provides data indicative thereof.

16. Apparatus according to claim 14 wherein the data supplied by the fourth means is a constant value.

17. Apparatus according to claim 11 wherein the second means comprises:

(a) a pulse detector; and,

(b) means coupled to the pulse detector for counting pulses.

18. Apparatus according to claim 11 wherein the second means comprises an ECG unit.

19. Apparatus comprising:

(a) a processor for determining a patient's metabolic rate ratio from data indicative of partial pressures of carbon dioxide and oxygen in the patient's arterial blood, the patient's heart rate and the patient's stroke volume;

(b) a first analog to digital converter coupled to the processor;

(c) a carbon dioxide analyzer coupled to the first analog to digital convertor for monitoring the amount of carbon dioxide exhaled by the patient;

(d) a second analog to digital converter coupled to the processor;

(e) an oxygen sensor coupled to the second analog to digital convertor for monitoring the amount of oxygen exhaled by the patient;

(f) a third analog to digital convertor coupled to the processor;

(g) means for supplying analog data indicative of stroke volume to the third analog to digital converter;

(h) a counter circuit means coupled to the processor for counting the patient's systolic pulse; and,

(i) a pulse detector coupled to the counter circuit means for monitoring the patient's systolic pulse signal.

20. Method of measuring a patient's metabolic rate ratio comprising the steps of:

(a) providing data indicative of oxygen and carbon dioxide concentrations of the patient;

(b) determining, based upon the data indicative of the patient's oxygen and carbon dioxide concentrations and data indicative of barometric pressure, the partial pressures of oxygen and carbon dioxide in arterial blood of the patient;

(c) determining, based upon the results of step (b), net effects of oxygen and carbon dioxide in the arterial blood on cardiac output of the patient;

(d) determining, based upon data indicative of cardiac output of the patient and the result of step (c), net effect of metabolic rate ratio on cardiac output of the patient; and,

(e) determining, based upon the result of step (d), the metabolic rate ratio of the patient and providing output data indicative thereof.

21. Method according to claim 20 further comprising the step of:

(a) providing data indicative of heart rate of the patient; and,

(b) providing data indicative of stroke volume of the patient, data indicative of cardiac output of the patient being obtained by multiplying the data indicative of stroke volume by the data indicative of heart rate.

22. Method according to claim 21 further comprising the step of substituting the data indicative of heart rate

with previously provided heart rate data when the data indicative of heart rate fails to fall within predetermined limits.

23. Method according to claim 20 wherein the data indicative of oxygen and carbon dioxide concentrations are provided by means of oxygen and carbon dioxide analyzers.

24. Method according to claim 23 wherein the partial pressures of oxygen and carbon dioxide in arterial blood of the patient are determined according to the following relationships:

$$PaCO_2 = Cco_2(P_B - 47) - K_1$$

$$PaO_2 = CO_2(P_B - 47) - K_2$$

Where:

(a) PaO_2 and $PaCO_2$ are the partial pressures of oxygen and carbon dioxide, respectively, in arterial blood of the patient in mmHg;

(b) Co_2 and Cco_2 are the volume concentrations of oxygen and carbon dioxide in exhaled gas of the patient, respectively;

(c) K_1 and K_2 are constants representing average differences between alveolar and arterial pressures of CO_2 and O_2, respectively, in mmHg;

(d) P_B is the barometric pressure in mm Hg; and,

(e) 47 is the partial pressure of water vapor in alveoli space in mmHg.

25. Method according to claim 20 wherein the data indicative of oxygen concentration is provided by means of a pulse oximeter.

26. Method according to claim 25 wherein the partial pressure of oxygen in arterial blood of the patient is determined according to the following relationship:

$$PaO_2 = \frac{-\ln[1 - (SaO_2)^4]}{0.046}$$

where:

(a) PaO_2 is the partial pressure of oxygen in the arterial blood of the patient in mmHg; and,

(b) SaO_2 is arterial hemoglobin oxygen saturation provided by the oximeter.

27. Method according to claim 20 wherein, when the partial pressure of carbon dioxide in arterial blood fails to exceed a predetermined threshold, the net effect of carbon dioxide in arterial blood on cardiac output is set to a pre-established value, and when the partial pressure of carbon dioxide in arterial blood exceeds the predetermined threshold the net effect of carbon dioxide in arterial blood on cardiac output is determined according to the following relationship:

$$Q'(CO_2) = 0.0045(PaCO_2 - N)$$

where:

(a) $Q'(CO_2)$ is the net effect of arterial pressure of carbon dioxide on cardiac output in liters per second;

(b) $PaCO_2$ is the partial pressure of carbon dioxide in arterial blood of the patient in mmHg; and,

(c) N is the value of the predetermined threshold in mmHg.

28. Method according to claim 20 wherein, when the partial presure of oxygen in the arterial blood of the patient exceeds a predetermined threshold the net effect of oxygen in arterial blood of the patient on cardiac output is set to a pre-established value, and when the partial pressure of oxygen in the arterial blood of the patient fails to exceed the predetermined threshold the net effect of oxygen in arterial blood on cardiac output is determined according to the following relationship:

$$Q'(O_2) = 244.509 \times 10^{-4} T_0(X) - 323.328 \times 10^{-4} T_1(X) + 105.044 \times 10^{-4} T_2(X) - 143.505 \times 10^{-5} T_3(X)$$

where:

(a) $Q'(O_2)$ is the net effect of arterial pressure of oxygen on cardiac output in liters per second;

(b) $T_j(X)$ is the Chebyshev polynomial of the first kind of degree (j) and argument (X);

(c)

$$X = \frac{2PaO_2 - 115}{65};$$

and,

PaO_2 arterial pressure of oxygen in mm Hg.

29. Method according to claim 2 wherein the net effects of oxygen and carbon dioxide in the arterial blood on cardiac output is determined according to the following relationship:

$$Q'_C = Q'(CO_2) + Q'(O_2)$$

where:

(a) Q'_c is the net effects of oxygen and carbon dioxide in arterial blood on the cardiac output;

(b) $Q'(CO_2)$ is the net effect of arterial pressure of carbon dioxide on the cardiac output; and,

(c) $Q'(O_2)$ is the net effect of arterial pressure of oxygen on the cardiac output.

30. Method according to claim 20 wherein the net effect of the metabolic rate ratio on the cardiac output of the patient is determined according to the following relationship:

$$\frac{dQ}{dT} = Q'_M + Q'_C$$

where:

(a)

$$Y = \frac{2MRR - 7}{5}$$

is the cardiac output or blood flow;

(b) Q'_M is the net effect of the metabolic rate ratio on the cardiac output; and,

(c) Q'_c is the net effects of oxygen and carbon dioxide in arterial blood on the cardiac output.

31. Method according to claim 20 wherein the metabolic rate ratio is calculated according to the following relationships:

$$Q'_M = 158.5674 \times 10^{-3} T_0(Y) + 617.519 \times 10^{-4} T_1(Y)$$

and

$$\frac{dQ}{dT}$$

where:

(a) Q'_M is the net effect of the metabolic rate ratio on cardiac output in liters per second;

(b) $T_j(Y)$ is the Chebyshev polynomial of the first kind and degree (j) with argument (Y); and,

(c) MRR is the metabolic rate ratio.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,909,259 Page 1 of 2

DATED : March 20, 1990

INVENTOR(S) : Fleur Taher Tehrani

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 7, line 43, "100K" should be --100--;

Col. 7, line 55, "Carciac" should be --Cardiac--;

Col. 8, line 1, "$p^{ACO}{}_2$" should be --$PaCO_2$--;

Col. 8, line 33, "O_{20}" should be --O_2--;

Col. 9, line 3, "Q'_m" should be --Q'_M--;

Col. 11, lines 22-23, "determined" should be --determine--;

Col. 11, line 52, "dates" should be --data--;

Col. 14, line 19, "2" should be --20--;

Col. 14, line 24, "$Q'c^{32}$" should be --Q'_c = --;

Col. 14, lines 42-47, "(a) $\frac{Y = 2MRR - 7}{5}$ is the cardiac output or blood flow" should be --(a) $\frac{dQ}{dT}$ is the cardiac output or blood flow"--;

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,909,259 Page 2 of 2

DATED : March 20, 1990

INVENTOR(S) : Fleur Taher Tehrani

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 14, line 60, "$\frac{dQ}{dT}$" should be -- $Y = \frac{2MRR - 7}{5}$ --.

Signed and Sealed this

Thirtieth Day of April, 1991

Attest:

HARRY F. MANBECK, JR

Attesting Officer

Commissioner of Patents and Trademarks